Egyptian Journal of Community Medicine, 2022;40(4): 243-250

Egyptian Journal of Community Medicine

Development and Validation of A Scale To Assess Hesitancy Towards New Vaccines

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Submission Date: 2022-01-08

Revision Date: 2022-02-15

Acceptance Date: 2022-02-23

Key Words: vaccine hesitancy, new vaccines, scale validation.

A B S T R A C T

Background: Assessing the hesitancy towards a new vaccine is of worldwide concern, as a delay in vaccination may give rise to the development of new mutant variants that can attack immunity conferred by previous infection or vaccine. **Objective:** This study aimed to design and validate a scale to assess the hesitancy towards newly produced vaccine based on health belief model traditional variables with application on COVID-19 vaccines. **Methods:** A cross sectional study was conducted among heterogeneous group of Egyptian citizens above 18 years old. A survey was distributed on social media platforms between June 1, 2021, and June 30, 2021. The design and evaluation of the scale went through three phases: item development, scale development, and evaluation. **Results:** The sampling adequacy of Kaiser-Meyer-Olkin measure was 0.8 at significance level of Bartlett's test of sphericity <0.001. Principal component analysis revealed 2 components. Component 1 was concerned with perceived benefits, while component 2 was concerned with perceived susceptibility, perceived severity, and perceived barriers. The variance of components 1 and 2 were 53.736% and 10.207% respectively with total variance 63.943%. Cronbach's alpha was 0.889 for component 1 and 0.921 for component 2. There was a significant moderate negative correlation between new vaccine hesitancy and intention to register to take the vaccine at correlation coefficient -0.6 and p-value <0.001. **Conclusion:** The designed scale to assess hesitancy towards new vaccines based on health belief model was valid among the studied population; also, it was a reliable scale according to Cronbach's alpha.

INTRODUCTION

Vaccination has a tremendous value and effect among public health interventions that has contributed to the eradication and elimination of many infectious diseases all over the world.[1] The widespread regular application of powerful vaccination programs succeeded in eradication of serious public health issue in several countries.[2] It is very hard to make a decision towards vaccination especially the new ones as it requires a multifaceted combination of cognitive, political, psychosocial, spiritual, and cultural factors. In many cases the interaction among these factors may result in vaccine hesitancy.[3] The vaccine hesitancy

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was simply defined by World Health Organization as a "delay in acceptance or refusal of vaccines despite availability of vaccination services".[4] Vaccine hesitancy is multifaceted as it is changeable across time and setting.[4]

Vaccine hesitancy has several causes which are multifaceted and encompass more than insufficient knowledge.[5] Reasons for vaccine hesitancy can be summarized into three main categories. The first is lack of trust in the vaccine regarding its effectiveness and safety. The second one is satisfaction or complacency as a result of perceived low risk. The last one is deficiency of convenience in the availability of vaccination services, or its accessibility, and the appeal for these services.[6]

Health beliefs and risk perception models are significant in studying decision making related factors by measuring what inspires and prevents people from following health related behaviour. Health Belief Model (HBM) has a tremendous role in assessing the relation between health behaviour and using different health facilities.[7]

HBM includes four main traditional variables which are perceived susceptibility, perceived severity, perceived benefits, and perceived barriers. Along with these traditional variables the HBM includes other independent variables which are self-efficacy, incentive to behave (health motivation) and cues to action.[8] HBM has been broadly utilized in different studies related to vaccination, and especially in the context of influenza vaccination. HBM was demonstrated in the findings of a systematic review studied the demographic and psychological factors related with influenza vaccine's uptake.[9]

The mission of SAGE Working Group on Vaccine Hesitancy was to define the vaccine hesitancy and its determinants and facilitate the development of tools to assess hesitancy issues and its nature.[10] Several tools were designed to assess vaccine hesitancy, but not to assess the hesitancy towards newly produced vaccines. Therefore, the objective of this study was to design and validate a scale to assess the hesitancy towards new vaccine based on HBM traditional variables with application on COVID-19 vaccines.

METHOD

A cross sectional study was conducted among heterogeneous group of Egyptian citizens living in Egypt above 18 years old. Inclusion criteria included Egyptian citizens above 18 years old who are not infected with COVID before nor registered to take the vaccine

A scale to measure the hesitancy towards a new vaccine was designed by the researchers with application on COVID-19 vaccine. The design of the scale and the evaluation went through three phases.

Phase I: Item development phase where domains were identified based on the four main constructs of HBM (perceived susceptibility, perceived severity, perceived benefits, and perceived barriers) and then item generation was conducted using the deductive approach. The questions' answers were presented on 5-point Likert scale ranging from strongly agree to strongly disagree.

The scale initially consisted of 12 questions distributed among 4 domains, 3 questions in perceived susceptibility, 3 questions in perceived severity, 2 questions in perceived benefits and 4 questions in perceived barriers. In addition to one question to assess the intention to register to take the vaccine in the next 3 months.

Content validity was measured to know the degree of representativeness of items to each domain in the questionnaire.[11]

Content validity was assessed by independent 6 experts in the field, three questions were added and modifications in the wording were done after their feedback. The number of questions reached 15, they were distributed among the 4 domains as following, 4 questions in perceived susceptibility, 3 questions in perceived severity, 4 questions in perceived benefits and 4 questions in perceived barriers, and the question which assess the intention to register to take the vaccine remained without change. After conducting the required modifications, the scale content validity index- Average (S-CVI/Ave) was one which is a good content validity.[12] S-CVI/Ave is considered to be excellent if it measures ≥ 0.9.[11]

The questions after validation of the content were as follows:

PS1*. I believe I am susceptible to ***the disease*** easily

PS2. I believe adherence to precautionary measures is sufficient to prevent infection

PS3. I believe the environment around me increases my chance of getting infected

PS4. I believe my natural immunity is enough to prevent infection

PSV1. I believe ***the disease******* is dangerous

PSV2. I believe the infection can cause permanent disability that affects life
PSV3. I believe infection with ***the disease*** may cause death
PB1. I believe vaccination relieves the symptoms of infection if you are exposed to infection
PB2. I believe vaccination prevents or reduces complications of infection
PB3. I believe vaccination allows me the freedom to travel and move in general
PB4. I believe vaccination protects me and those around me
PBR1. I believe vaccination has a long waiting list
PBR2. I believe vaccination has side effects
PBR3. I believe my health condition prevents me from being vaccinated
PBR4. I believe vaccination is not safe

**PS is perceived susceptibility, PSV is perceived severity, PB is perceived benefits and PBR is perceived barriers.*
*** **"The disease"** was substituted with COVID-19 as the application of the scale was on COVID-19*

Table (1): Sociodemographic characteristics of the participants

Variable	Mean±SD
Age	36.4±9.7
Range	(21-70)
	N (%)
Gender	
• Male	120 (36.4)
• Female	210 (63.6)
Residence	
• Rural	105 (31.8)
• Urban	225 (68.2)
Level of education	
• Elementary	20 (6.1)
• High school	25 (7.6)
• Bachelor	140 (42.4)
• Postgraduates	145 (43.9)
Working status	
• Working	250 (75.8)
• Not working	80 (24.2)
Total	330

Phase 2: Scale development where pretesting of the scale was conducted among a sample of the target group to ensure the maximum understanding of questions. To calculate the sample size, the rule of thumb has been suggested to be at least 10 participants for each scale item[13], however others suggested that a sample of 300 is classified as a good sample for factor analysis.[14] Sample size of this research reached 330. Then sample size adequacy was tested using KMO and Bartlett's test of sphericity where proceeding to factor analysis is allowed, if the value of Kaiser-Meyer-Olkin (KMO) is more than 0.6 and the test of sphericity level of significance at $\alpha < 0.05$ [(13)].

Table 2: Sample Size Adequacy.

Kaiser-Meyer-Olkin Measure of Sampling Adequacy.		0.828
Bartlett's Test of Sphericity	Approx. Chi-Square	2112.831
	df	45
	Sig.	<0.001

Item reduction analysis was done using inter item correlation to measure the extent of relation between one item and all other items in the scale to detect the items that are not concerned with the scale. The determinant of the inter correlation matrix was 0.00 which reflects high collinearity[15], hence we kept 10 questions with correlation coefficient between 0.3 and 0.8. After deletion of the low correlated questions, determinant increased to 0.001.
Cattel's Scree test was used to determine the number of factors to be extracted, 2 factors were extracted which had an eigenvalue greater than 1.[16]

Phase 3: Scale evaluation

Principal factor analysis was conducted using Varimax Rotation and Kaiser Normalization. The cutoff for the loading was set at 0.3. The communality value above 0.3 is indicating that the factor fit well in the factor analysis [(17)]. The total variance explained by the model was calculated and values ≥ 60% were appropriate [(18)]. Reliability of the extracted factors was tested using Cronbach's alpha. Where values more than 0.7 are acceptable and above 0.9 are the best [(19)]. Convergent validity was tested by testing the correlation between the total vaccine hesitancy of the final version of the scale with one question assessing the intention to register to take the vaccine in the next 3 months.
The final questions of the scale were as follows:
PS1. I believe I am susceptible to ***the disease*** easily
PS2. I believe the environment around me increases my chance of getting infected
PSV1. I believe ***the disease*** is dangerous

Table 3: Principal Component Analysis of Vaccine Hesitancy Scale.

Rotated Component Matrix			
	Component		
	1	**2**	**Communality**
PB1. I believe Vaccination relieves the symptoms of infection if you are exposed to infection	0.866		0.822
PB2. I believe Vaccination prevents or reduces complications of infection	0.864		0.800
PB4. I believe Vaccination protects me and those around me	0.862		0.807
PB3. I believe Vaccination allows me the freedom to travel and move in general	0.811		0.759
PS1. I believe I am susceptible to the disease easily		0.735	0.567
PSV1. I believe the disease is a dangerous		0.724	0.615
PS3. I believe the environment around me increases my chance of getting infected		0.692	0.506
PSV3. I believe Infection with the disease may cause death		0.619	0.733
PBR2. I believe Vaccination has side effects		-0.471	0.315
PSV2. I believe the infection can cause permanent disability that affects life		0.433	0.470
Variance *	53.736	10.207	
Cronbach's alpha	0.889	0.921	
Extraction Method: Principal Component Analysis. Rotation Method: Varimax with Kaiser Normalization.			
Rotation converged in 3 iterations. Total variance = 63.943			

Table 4: Description of vaccine hesitancy regarding different domains of HBM and intention to register

	Median (Range)
Perceived susceptibility	4.5 (2-8)
Perceived severity	6 (3-12)
Perceived benefits	8 (4-20)
Perceived barriers	4 (1-5)
Total vaccine hesitancy	38 (25-57)
Intention to register to take the vaccine	3 (1-5)

PSV2. I believe the infection can cause permanent disability that affects life

PSV3. I believe infection with ***the disease*** may cause death

PB1. I believe vaccination relieves the symptoms of infection if you are exposed to infection

PB2. I believe vaccination prevents or reduces complications of infection

PB3. I believe vaccination allows me the freedom to travel and move in general

PB4. I believe vaccination protects me and those around me

PBR1. I believe vaccination has side effects

PS is perceived susceptibility, PSV is perceived severity, PB is perceived benefits and PBR is perceived barriers

Data collection

Data were collected through distribution of an online survey between June 1, 2021, and June 30, 2021, on social media platforms (facebook and whatsapp) to ensure participation of large scale of Egyptians. If the participant has registered to take the vaccine or already took the vaccine the questionnaire is automatically submitted.

Statistical analysis

Data was analyzed using SPSS version 25, IBM Corp (NY, United States). All questions in the final version were reversed scoring except the question concerned with perceived barrier. The higher the score the higher is the vaccine hesitancy. Before conducting factor analysis, the adequacy of sample size was tested using KMO where a value 0.8 to 1 means that the sample is adequate and the data suits to undergo factor analysis.[20] KMO value between (0.7-0.79) are middling and between (0.6-0.69) is mediocre. KMO value below 0.6 means that data do not suit to undergo factor analysis. Also, Bartlett's test of sphericity was conducted to indicate if the factor analysis is worthy at a significant level less than 0.05 which reflects the

Table 5: Correlation between new vaccine hesitancy domains and intention to register to take the vaccine

Total vaccine hesitancy			Intention
Total vaccine hesitancy	r*		-.0.6
	p		<0.001
Intention	r*	-0.6	
	p	<0.001	
Perceived susceptibility	r*	0.5	-0.4
	p	<0.001	<0.001
Perceived severity	r*	0.7	-0.3
	p	<0.001	<0.001
Perceived benefits	r*	0.7	-0.7
	p	<0.001	<0.001
Perceived barriers	r*	0.01	0.1
	p	0.8	0.1

*Spearman correlation is used

correlation between the variables that are introduced in the factor analysis.[20]

Principal component analysis was conducted with varimax rotation and kaiser normalization to avoid cross loading of the variables between the 2 components. Loading value > 0.3 is significant which means that the variable is important in the interpretation of the component.[21]

RESULTS

It was found that 36.4% of the participants were males and 63.6% were female. The mean age was 36.4+9.7 with minimum age 21 and maximum 70. The level of education varied across the participants and categorized in 4 groups; elementary school, high school, bachelor and postgraduates and the population was represented by 6.1%, 7.6 %, 42.4% and 43.9 respectively. The participants distributed between rural and urban areas by 31.8% and 68.2 % respectively. 24.2% were not working and 75.8% were working (Table 1)

Table 2 shows that the sampling adequacy of KMO is 0.8 at significance level of Bartlett's test of sphericity <0.001

Table 3 shows that component 1 consisted of 4 questions related to perceived benefits where the loading of the questions (PB1. I believe vaccination relieves the symptoms of infection if you are exposed to infection, PB2. I believe vaccination prevents or reduces complications of infection, PB4. I believe vaccination protects me and those around me, PB3. I believe vaccination allows me the freedom to travel and move in general) were 0.866, 0.864, 0.62 and 0.11 respectively at communality values 0.822, 0.800, 0.807 and 0.759 respectively. On the other hand, the second component consisted of the questions related to perceived susceptibility, perceived severity, and perceived barriers. The loading of the perceived susceptibility (PS1. I believe I am susceptible to the disease easily, PS2. I believe the environment around me increases my chance of getting infected) were 0.735 and 0.692 respectively at communality values 0.567 and 0.506 respectively. The loading of the perceived severity questions (PSV1. I believe the disease is a dangerous, PSV3. I believe infection with the disease may cause death, PSV2. I believe the infection can cause permanent disability that affects life) were 0.724, 0.619, and 0.433 respectively at communality value 0.615, 0.733 and 0.470 respectively. The loading of the perceived barrier question (PBR1. I believe vaccination has side effects) was -0.471 at communality value 0.315. The variance of components 1 and 2 were 53.736% and 10.207% with total variance 63.943%.

Cronbach's alpha was 0.889 for component 1 and 0.921 for component 2.

Table 4 shows that the median for perceived susceptibility, perceived severity, perceived benefits and perceived barriers is 4.5,6,8 and 4 respectively with range (2-8, 3-12, 4-20 and 1-5) respectively. The median for total vaccine hesitancy and intention is 38 and 3 respectively with range (25-57 and 1-5) respectively

Table 5 shows that there is significant moderate negative correlation between intention to register to take the vaccine and total vaccine hesitancy, perceived susceptibility, perceived severity at correlation coefficient -0.6, -0.4, -0.3 respectively with p-value <0.001, <0.001 and <0.001 respectively. Also, strong negative significant correlation was detected between intention to register to take the vaccine and perceived benefits at correlation coefficient -0.7 at p value <0.001. On the other hand, there is significant positive strong correlation between total vaccine hesitancy and perceived severity and perceived benefits at correlation coefficient 0.7 and 0.7 respectively with p value <0.001 and <0.001 respectively. Also, there is significant moderate positive correlation between total

vaccine hesitancy and perceived benefits at correlation coefficient 0.5 and p value <0.001. There is no correlation between perceived barriers with total vaccine hesitancy nor intention to register to take the vaccine.

DISCUSSION

Vaccine hesitancy is recognized to be one of the public health concerns.[22] Clinical development of new vaccines passes through three phases and then approval and licensing process of the vaccine takes place.[23] It is very important to consider the vaccine perception of public towards the new vaccine as it will control its uptake. Understanding vaccine hesitancy will drive decision makers to develop vaccine hesitancy reducing strategies.[24]

The aim of this study was to design and validate a scale to measure the hesitancy towards new vaccine based on HBM traditional variables with application on COVID19 vaccines. Up to our knowledge, this is the first study in our region to develop tool to measure hesitancy to new vaccines.

In the current study, the authors designed a scale based on the 4 main constructs of health belief model. HBM has been used to evaluate attitudes and beliefs towards many vaccines such as influenza vaccine[25,26], Nevertheless, no studies have emphasized on the use of the model to predict the acceptance of newly produced vaccine.

The current research was conducted in Egypt when COVID 19 vaccine uptake was obligatory only for health care workers and military and police personnel. As it is essential to ensure the generalization of the scale, it must be applied on heterogenous population. This study fulfilled this requirement by conducting the scale on a heterogeneous group of Egyptian citizens.[27]

The analysis of validation of the survey went through three stages

1. Suitability of the data for factor analysis:

The study was carried out on 330 Egyptian citizens, with sampling adequacy of KMO 0.8 which was significant at Bartlett's test of sphericity (<0.001). This indicates that sampling is meritorious and adequate[28] and it is suitable to undergo factor analysis. Five (5) questions were removed from the analysis because the determinant score was less than 0.00001 which reflects the multicollinearity. The 5 questions of low correlation were removed, and the determinant score became 0.001 which indicates absence of multicollinearity.[20]

2. Factor extraction and interpretation

The results of principal component analysis of the current study revealed a two-component structure scale, The first component consisted of 4 items representing perceived vaccine benefits and the second one consisted of 6 items representing perceived susceptibility, perceived severity and perceived barriers which reflects that the answers of component 2 were correlated in the perceived cons of the vaccine while the answers of component 1 presented the perceived pros of it that affects the vaccine acceptance.

The extraction of the components was done by Scree test and the cutoff for loading of variables was set at 0.3. The research revealed that the 2 components explained 63.9% of the total variance which should be at least 50% which indicate good contribution of the variables within each component to factor analysis.[20]

According to a former study[29] which reported that Cronbach's alpha value between 0.8 and 0.95 is one of the factors acknowledging the psychometric properties of a scale. The present study revealed that, Cronbach's alpha was 0.889 for component 1 and 0.921 for component 2 which reflects good reliability.

3. Assessment of convergent validity

Regarding the convergent correlation between new vaccine hesitancy and the intention to register to take the vaccine, this study revealed significant moderate negative correlation at spearman correlation coefficient -0.6 and P value <0.001 which was supported by another study[30] that was conducted in USA and reported significant correlation between perceived susceptibility and willing to vaccinate.

CONCLUSION

The designed scale to assess hesitancy towards new vaccines was valid and reliable scale. It is recommended to conduct this scale on different countries to ensure the validity of the scale in other populations.

Strengths and limitations

The strength of the current research lies within that being the first to develop and validate an instrument assessing the hesitancy to towards a newly produced vaccine's uptake. However, few limitations were recognized. The first is that the survey was launched

through social media platforms due to application of COVID 19 restrictive precautions, however reaching to a heterogenous population was achieved and the safety of the researchers and the participants was ensured. The second limitation was that we had used convenience sampling technique, therefore, the results of the study can be projected only on population of similar characteristics.

Funding Source

The authors received no financial support related to this research

Declaration of Interest

Authors reported no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgment

Authors appreciate the feedback of the experts who evaluated the content validity of the scale: Dr Anwar AlHashem; Princess Nourah Bint Abdelrahman University, Dr Samira Marey; Princess Nourah Bint Abdelrahman University, Dr Howeida AbuSalih; Princess Nourah Bint Abdelrahman University, Dr Omnia ElSeifi Zagazig; university, Dr Amany Abu El-soeud; Zagazig university, Dr Ghada ElSharkawy; Zagazig university and Dr Hosnia Ragab; Zagazig University.

Ethical consideration

The research proposal was approved by the institutional review board (IRB #7071). The purpose of the research was clarified in the electronic survey. Anonymity of the participants were preserved.

Author contributions:

Huny Bakry: Idea, literature search, analysis and writing; Noha Abdelsallam: Idea, literature search, and writing; Eman Waly: Idea, literature search, and writing

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Cite this article as: Huny Mohamed Amin Bakry, Development and Validation of A Scale To Assess Hesitancy Towards New Vaccines. *Egyptian Journal of Community Medicine* 2022;40(4):243-250.
DOI: **10.21608/ejcm.2022.115288.1203**