

ORIGINAL ARTICLE

QUESTIONNAIRE DEVELOPMENT ON RISK PERCEPTION IN BASIC CHILDHOOD VACCINATION: A VALIDATION STUDY ON PREGNANT MOTHERS IN MALAYSIA

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ABSTRACT

Quantitative study on risk perception in vaccination encompasses various theoretical basis, health context, and psychometric validity and reliability. In the context of basic childhood vaccination, there was a lack of locally validated and reliable instrument to measure risk perception for vaccine-preventable disease. As such, this study aimed to validate and assess reliability of developed instruments in Malay language. Items were generated from available items in previous research and adopting recommendations on operationalising the construct. Generated items were measured for content validity index by seven experts, tested for factorial validity using exploratory (EFA) and confirmatory factor analysis (CFA) using structural equation modelling. Reliability was established using Cronbach's alpha. Seven items measured perceived likelihood whereas eight items measured perceived severity. Reliability index was 0.97 for perceived likelihood and 0.94 for perceived severity. CFA on second-order measurement model revealed satisfactory model fit χ^2/df (1.55), CFI 0.96, TLI 0.95, and RMSEA 0.11. The average variance explained was 0.73 for perceived likelihood and 0.73 for perceived severity and CR was 0.95 and 0.96 for perceived likelihood and perceived severity, respectively. Both constructs showed significant positive correlation ($r = 0.19$, $p < 0.01$) with each other indicating divergent validity. Thus, the Malay risk perception questionnaire established good content, factorial, and divergent validity, as well as good reliability on Cronbach's alpha. The instrument should be valuable to re-examine risk perception's role in the resurgence of vaccine hesitancy in the local population.

Keywords: Risk Perception, Questionnaire Validation, Vaccination, Structural Equation Modelling

INTRODUCTION

Basic childhood vaccination has been hailed as the greatest public health intervention, contributing to the reduction of vaccine-preventable disease (VPD) incidence, mortality rate, and eradication of certain VPD. The benefits of basic childhood vaccination also extends to the improvement in public productivity (e.g.: lower disability or time out of school) and cost savings in resources required for the treatment of VPD¹. World Health Organization recommends vaccination against ten VPDs for all children, three VPDs for children living in certain regions, six VPDs for children in high-risk population, and three VPDs for children with specific characteristics². In Malaysia, the National

Immunization Programme (NIP) provides protection against ten VPDs for all children under 2 years and three VPDs for children above 2 years old from high-risk population or with specific characteristics³. Currently, the Malaysian NIP has achieved vaccination coverage for more than 90% across all VPDs for children under 2 years old⁴. However, this success has been opined to be its own weakness, that is: herd immunity contributed to low awareness of risk on VPDs and subsequent rise of vaccine hesitancy⁵⁻⁷.

Risk perception plays an important role for individual and public health. Health Belief Model (HBM) propose perceived likelihood and severity of disorder, perceived benefit of action, and barriers to act in the model^{8,9}.

Other theory such as the Extended Parallel Process Model (EPPM) describes risk perception only as perception on likelihood and perception on severity of the disease¹⁰. Conceptualization of risk is more extensive in HBM as compared to EPPM which limits the risk perception to disease/disorder.

In a different theoretical perspective, Ferrer & Klein (2015) has described risk perception into deliberative, affective and experiential dimensions. Deliberative risk perception explains the systematic evaluation of facts. Affective risk perception is the emotion attached to the risk. Finally, experiential risk perception is related to the accessibility to the contents of deliberative and affective risk perception at times of decision-making. Intervention that targets affect has been shown to significantly predict preventive health behaviour. Comparison of the two perspectives suggested that most of the constructs under HBM and EPPM subscribed to the deliberative risk perception.

Majority of the previous quantitative studies have measured risk perception according to Health Belief Model (HBM) dimensions^{8,13-23}. The use of quantitative measures in the above studies have mixed level of reliability and validity. Several studies have not reported any form of reliability and validity of the items they used in their study^{13,24,25}. Considering risk perception is an unobservable concept, there is a need to establish the psychometric value of items used as proxy to measure the concept²⁶. Other researches that do report method to establish validity, unfortunately lack in reliability either due to technical error in choosing reliability technique or poor reliability index^{16,18}. Another noticeable issue with some of the studies are the use of single item on either single scale or multiple scale to measure one specific concept. This precludes tapping all risk perception perspectives as discussed above²⁷. The use of multiple scale in the response of a single item questionnaire may improve reliability but reducing content validity for risk perception. Several of their instruments were built to assess risk perception towards specific disease such as influenza and human papilloma virus. Thus, a different measure to assess risk perception for basic childhood vaccination is needed. As vaccine hesitancy or refusal showed an increasing trend in Malaysia²⁸, it is worth

revisiting Malaysian parent's risk perception towards VPD and vaccination. This will allow appropriate health promotional activities to be planned. Availability of an established instrument will allow research into the role of risk perception in current vaccination scenario.

Other than considering the psychometric properties of a questionnaire, Brewer et al. (2007) suggested that items measuring perceived likelihood or susceptibility of VPD must be conditioned in "no vaccination" and within a timeframe. Without such condition, parents that have already vaccinated their children will perceive reduced risk as prevention had been taken. This will distort findings and reflect incoherence with theory. Measures of risk perception should also include affect-associated items as lay person perceived risk in both cognitive and affective dimension^{30,31}. Weinstein et al. (2007) added that affective items predicted preventative action better than cognitive items amongst parents.

As such, this study aims to develop, establish validity and reliability of risk perception questionnaire on basic childhood vaccination based on the above recommendations.

METHODS

A search strategy was used to identify literatures that include measures to assess risk perception in vaccination. The items from each study were aggregated according to their dimension (whenever possible) and were used as guide to generate the items measuring risk perception. Some qualitative studies that investigate risk perception were also included to add value in generating items for risk perception. The steps for developing instruments followed the methodology outlined by Kumar (2016)³³. In this study, items were generated for perceived likelihood and perceived severity as it is the common dimension held across theoretical perspectives as discussed above. Nine items for perceived likelihood and nine items for perceived severity were generated. All items were generated in English before being back-to-back translated into Malay. One subject matter expert and one linguist, fluent in both languages, independently translated the items into Malay. The two Malay drafts were discussed, and any differences were

ameliorated to form a final Malay draft. The final Malay draft was back translated into English by a linguist blinded to the purpose of the instrument. Original English, final Malay draft, and back translated draft were discussed, and consensus was achieved on the final Malay item wording.

The items were reviewed by seven experts consisting of a family medicine specialist, senior nurse in family health, public health medical officer, paediatric registrar, research nurse and psychologists. Each expert rate the relevance of the items and gave their opinion regarding the wording and suitability of the item. Relevance ratings range from 1 until 4 with higher number reflect higher relevance. All opinions were discussed by the authors of the paper and necessary actions were taken. Content Validity Index (CVI) was calculated for Item-related CVI (I-CVI) and Scale-related CVI (S-CVI). Scale-related CVI utilised S-CVI/Ave. Items I-CVI > 0.8 was accepted as item for pilot questionnaire. Items I-CVI 0.5 - 0.79 were reviewed by authors based on given suggestions or comments of expert.

All modified items were administered in the exploratory study on randomly chosen samples from primary and rural health clinics in districts of Petaling, Klang, Gombak and Hulu Langat. A convention of 1:10 was used to calculate minimum sample size needed³⁴. Respondents fulfilling these characteristics were included: (a) Malaysian mothers, (b) pregnant, (c) married, and (d) able to read and write. Pregnant mother is one of the target population for intervention in National Immunisation Promotional Campaign and previous research has shown that empowering mothers lead to positive vaccination uptake^{35,36}. Respondents with (a) sexual assault history or (b) active mental illness was excluded to prevent harm. Confirmatory study was done on similar population and sampling process. Soper's A-priori sample size calculator was used to determine minimum sample size needed³⁷. Respondents were chosen using systematic random sampling and the questionnaire was self-administered face-to-face. Same inclusion and exclusion criteria were used. The final questionnaire comprised of demographic information, and risk perception items in two dimensions: (a) perceived likelihood (seven items) and (b) perceived severity (eight items). All items

scored on a 7-point interval scale with each extreme is defined as "Strongly Disagree" and "Strongly Agree", respectively. Score for each dimension was calculated from the summation of response. Higher total score reflects higher perception of that dimension.

Statistical analysis

Descriptive analysis was done on demographic characteristic of respondents using SPSS version 27.

Exploratory factor analysis utilised principal component analysis based on Eigenvalues > 1.0 and Varimax rotation using Statistical Package for Social Sciences (SPSS) version 27. Reliability index was calculated using Cronbach's alpha or corrected item-total correlation as appropriate. Items were removed to achieve reliability index > 0.7 on Cronbach's alpha or having < 0.3 on corrected item-total correlation. Items fulfilling the criteria above were retained for confirmatory factor analysis (CFA).

Factorial validity was established using confirmatory factor analysis in SPSS Amos version 27. Maximum likelihood estimation was used after fulfilling relevant multivariate statistical assumptions. Goodness-of-fit was assessed according to several fit indices such as $\chi^2/df < 3.0$, comparative fit index (CFI) > 0.90, Tucker-Lewis's index (TLI) > 0.90, and root mean-square error of approximation (RMSEA) < 0.08. Reliability was established using Cronbach's alpha. Pearson's correlation was used to established divergent validity between perceived likelihood and perceived severity.

Ethical approval

Ethical approval was obtained from Medical Research Ethics Committee [NMRR-19-4053-50796 (IIR)] and Universiti Sains Malaysia Ethics Review Board [USM/JEPeM/19100566].

RESULT

A total of 108 respondents answered the questionnaire for exploratory study and 416 respondents answered the questionnaire for confirmatory study. Majority of respondents in the confirmatory study were Malays with 338 respondents (84%), has university-level education (68.8%), earn less than RM 6,000 per month (72.6%), and household income of less than RM6,000 (71%). Majority of respondents

has one or two child (59.3%), and a significant portion has no child (26.6%). Table 1

summarise the demographics of the confirmatory study respondents.

Table 1: Demographic details

Demography	N	%	Mean (SD)
Age			30.56 (4.90)
Ethnicity			
Malay	338	84	
Chinese	24	6	
Indian	24	6	
Indigenous	16	4	
Education level			
Primary school	6	1.5	
Secondary school	104	25.2	
Vocational Certificate	18	4.4	
Diploma	104	25.2	
Degree	148	35.9	
Master	29	7.0	
PhD	3	0.7	
Personal Income			
No income	89	21.6	
Less than RM 3,000	183	44.4	
RM 3,001 to RM 6,000	116	28.2	
RM 6,001 to RM 9,000	21	5.1	
RM 9,001 to RM 12,000	3	0.7	
Household Income			
No income	1	.2	
Less than RM 3,000	114	28.4	
RM 3,001 to RM 6,000	170	42.4	
RM 6,001 to RM 9,000	69	17.2	
RM 9,001 to RM 15,000	34	8.5	
More than RM 15,000	8	2.0	

Content validity index

Out of proposed nine items generated for perceived likelihood, five items achieved I-CVI score of 0.80 and above. Other items scored 0.71 were modified according to suggestion. For perceived severity, out of the nine items generated, eight items achieved I-CVI score of 0.80 and above. One item scored 0.71 was modified according to suggestion. Table 2 above summarize the content validity index after modified items were revalidated. One item (PLQ9) was dropped as no improvement in I-CVI score after modification. Scale-related CVI for perceived likelihood and perceived severity was calculated after removing dropped item, reporting an index of 0.94 and 0.95, respectively.

Exploratory factor analysis

Kaiser-Meyer-Olkin measure of sampling adequacy was 0.898 and Bartlett’s Test of Sphericity was significant. Exploratory factor analysis revealed three factors exist when all items were tested. All loaded onto the theorized factors except for PLQ8 and PSQ8. Both items were removed, and the remaining items were reanalysed to produce results as shown in Table 2 below. All items showed corrected item-total correlation > 0.3 showing good internal consistency. This was also reflected in Cronbach’s alpha value of 0.97 and 0.94 for perceived likelihood and perceived severity, respectively. The cumulative variance explained by the two factors was 77.75 %.

Table 2: Final content validity indices and EFA result for risk perception items

Dimension	Item Code	I-CVI	S-CVI/Ave*	λ	Corr. item-total correlation	Cronbach's α
Perceived likelihood	PLQ1	0.86	0.94	0.74	0.71	0.97
	PLQ2	1.00		0.92	0.89	
	PLQ3	1.00		0.94	0.92	
	PLQ4	1.00		0.92	0.91	
	PLQ5	0.86		0.96	0.95	
	PLQ6	0.86		0.94	0.92	
	PLQ7	0.86		0.94	0.92	
	PLQ8	0.86		R	R	
	PLQ9	0.71		R	R	
Perceived severity	PSQ1	1.00	0.95	0.88	0.85	0.94
	PSQ2	1.00		0.81	0.75	
	PSQ3	1.00		0.87	0.84	
	PSQ4	0.86		0.94	0.91	
	PSQ5	0.86		0.94	0.91	
	PSQ6	1.00		0.80	0.78	
	PSQ7	0.86		0.67	0.64	
	PSQ8	0.86		R	R	
	PSQ9	1.00		0.68	0.58	

*S-CVI/Ave excludes items with I-CVI less than 0.80

R - item removed; λ - factor loading; α - Cronbach's alpha

Confirmatory factor analysis

Confirmatory factor analysis revealed all factor loadings were above 0.70 (refer Figure 1 below). The initial model fit was not satisfactory on several indices. The χ^2/df (6.11) was higher than maximum cut-off of 3, comparative fit index (CFI) 0.94 was satisfactory, Tucker-Lewis's index (TLI) 0.93 lower than cut-off value 0.95, and root mean-square error of approximation (RMSEA) 0.11 which is higher than cut-off value 0.08.

Modification indices reported several residual covariances within items under similar factor. Modification to the model resulted in a better model fit: χ^2/df (1.55), CFI 0.96, TLI 0.95, and RMSEA 0.11. The average variance extracted was 0.73 for perceived likelihood and perceived severity reflecting good convergent validity between the measurement model and data. Composite reliability was 0.95 and 0.96 for perceived likelihood and perceived severity, respectively.

Correlation coefficient between perceived likelihood and perceived severity was 0.19 ($p < 0.01$), thus establishing significant relationship between the dimensions but sufficiently different from each other.

DISCUSSION

The data validation of this study is from the following sample characteristics. Data was obtained from almost exclusively Malays. Respondents have university-level education (diploma or degree) and with significant representation from those with secondary school-level education. Personal income was represented almost equally from no income, less than RM 3,000 and RM 3,001 to RM 6,000. Household income reported significant representation from earning less than RM 3,000 with a fifth respondents without any household income. Majority of mothers do not have other children, which may indicate first pregnancy (as suggested by lower median or mean age among them). Theoretically, they do not have any prior experience in deciding for child vaccination.

The generality of items generated allow the instrument to be used in different vaccine-preventable disease scenario. For example, in the COVID-19 vaccination programme for school children, this instrument can be utilised to understand how risk perception contributes to COVID-19 vaccination acceptance by parents. In addition, there were several

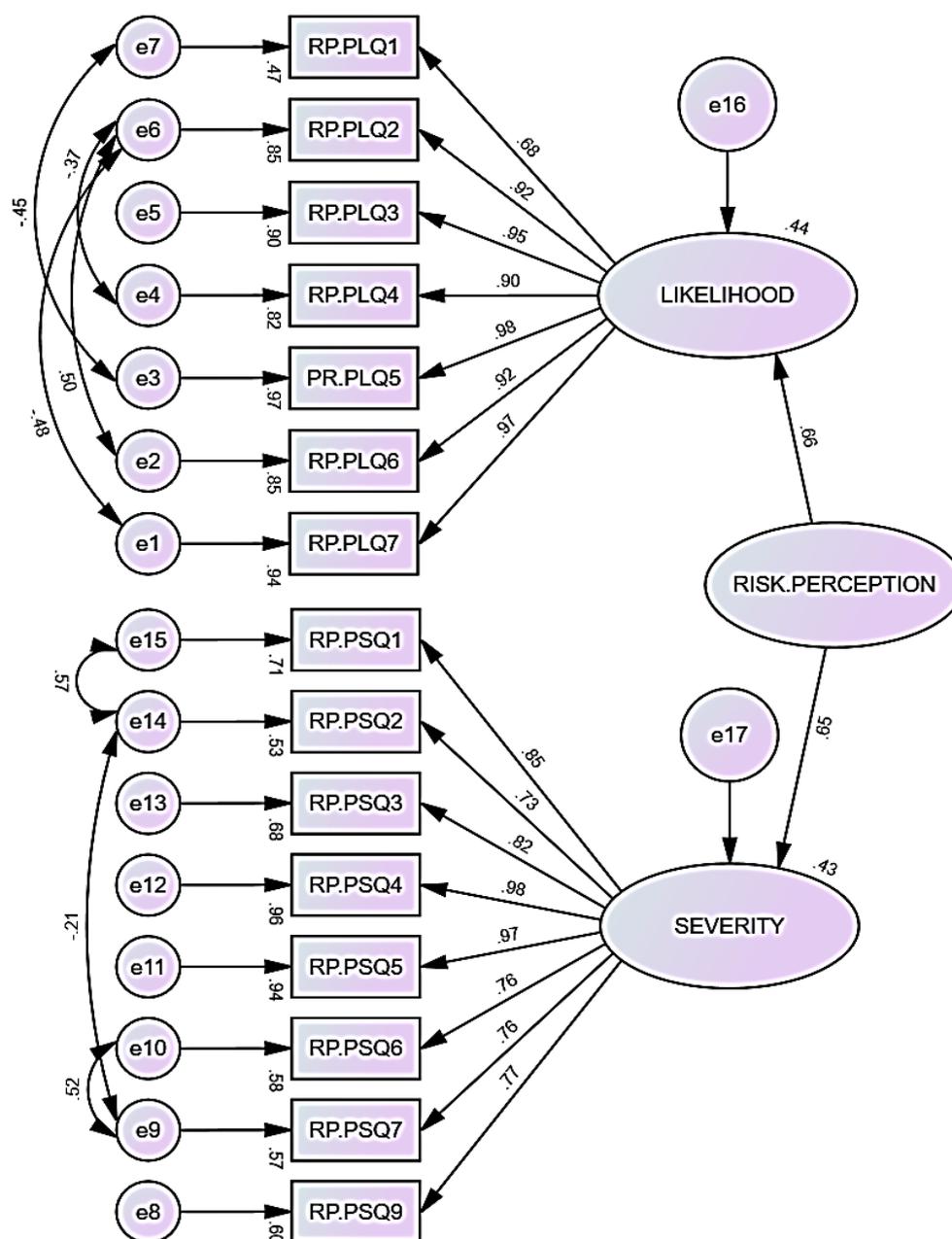


Figure 1: Measurement model for confirmatory factor analysis

vaccines for infection which are common in Malaysia (e.g.: varicella zoster or dengue) yet to be included in the routine vaccination schedule. This instrument will allow exploration of parent’s risk perception towards these infections before considering implementation of new vaccination schedule or in selected high-risk population. Authorities can use knowledge on risk perception in planning logistic needs and their promotion strategies. As introduced above, risk perception is a blend of an objective and subjective estimation. The developed items tap into both the objective and subjective

process, with specific attention to emotions commonly associated with vaccination uptake. This will allow more holistic representation of the construct.

For preventative action, perceived likelihood is a stronger factor than perceived benefits. Perceived severity is the least factor in predicting health behaviour^{9,11}. However, parents have reported difficulties in understanding knowledge related to risk perception^{38,39}. For example, the use of description to deliver risk perception (e.g.: uncommon or rare) often confusing to parents⁴⁰. Parents were able to estimate risk

better when risk is presented in percentage, as opposed to frequency or graph³⁹. This is expected as interpretation of frequency depends on the context of population. Same frequency but different population size translates to different risk estimates. Other studies have also established that parents also have preference for the type of risk information⁴¹. Those from lower education level consider duration of protection (perceived efficacy, a subset of risk perception not developed in this study) as most important. Whereas those from higher education level rate perceived efficacy and perceived likelihood of adverse reaction as more important. Future research to determine crucial risk information and preferred description format within the local population may benefit from this instrument.

Available basic childhood vaccination studies often focus on knowledge, attitude, and practice^{36,42,43}. Lack attention was given to other variables important for vaccination-related outcomes in local research. The availability of this instrument enables us to expand our understanding on vaccination beyond knowledge and attitude. This is in line with experts' recommendation that research and intervention should consider psychological attributes to understand the decision-making process in accepting childhood vaccination⁴⁴⁻⁴⁶. Local report has quoted reasons such as influenced by internet or social media, terrible experience, and doubts on effectiveness of vaccine were common in vaccine refusal parents⁴⁷. These reasons have relation to formation of risk perception^{48,49}.

Confirmatory study was done involving all randomly chosen sampling sites. However, the ethnic distribution of the samples was not representative of the whole Selangor state. There was also significant aggregation of certain ethnicity in certain districts and locations within district. Future research should either focus on sites with higher population of other ethnicity (eg: Chinese and Indian) or employed a quota sampling method to select respondents. Data from such studies can provide cross-validation to the existing data.

Item generation was done using previous literatures as basis for reference instead of qualitative methods on target population. Therefore, there may be a chance for some

perspective of perceived likelihood or perceived severity not measured by the current items by virtue of cultural differences. Future research should consider qualitative methods with quota sampling of parents based on their children vaccination history. Such sampling method will allow breadth of items encompasses perception that present across health actions.

CONCLUSION

Items measuring risk perception in basic childhood vaccination showed good content validity with experts. Factorial validity was established on EFA and CFA. The instrument reported acceptable reliability on Cronbach's alpha. Risk perception should be considered in future research especially in the current rise of vaccine hesitancy and refusal among parents.

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Conflict of interest

I declare no conflict of interest with the outcome of research.

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