ABSTRACT

INTRODUCTION: Parental hesitancy towards routine childhood vaccines has been recognized as one of the public health threats. Since the uptake of child vaccination remains inconsistent, there is a need for a reliable and validated tool to measure this phenomenon. MATERIALS AND METHODS: A cross-sectional study was conducted at government health clinics in Kelantan between April 2023 to July 2023. A permission to use the original version of Modified Vaccine Hesitancy Scale (MVHS) was obtained and translated into the Malay version (MVHS-M) based on established guidelines. Parents who have at least one child aged 7 years or less were recruited by using systematic random sampling to validate the MVHS-M. A confirmatory factor analysis (CFA) was used to confirm the latent domain, while reliability was measured by composite reliability and test-retest. The data were analysed using IBM SPSS Version 26 and Mplus version 8. RESULTS: A total of 270 parents who fulfilled the study criteria were selected and completed the survey. The CFA showed a good fit index: RMSEA=0.057 (90% CI 0.031, 0.082), CFI=0.970, TLI=0.957, and SRMR=0.031. The composite reliability for the domain "lack of confidence" was 0.93 (95% CI 0.91, 0.94), while the domain "risk" showed a reliability of 0.74 (95% CI 0.69, 0.79). The test-retest reliability, as measured by the Intra-class Correlation Coefficient (ICC), was 0.77 (95% CI 0.59, 0.87), indicating good stability. CONCLUSION: MVHS-M is a valid and reliable tool that will be useful in identifying parental vaccine hesitancy in Malaysia.

INTRODUCTION

Vaccines saved millions of children's lives every year.1 The eradication of smallpox and near-elimination of polio are well-known success stories resulting from the worldwide implementation of immunization programs. In Malaysia, since the introduction of the National Immunization Program (NIP) in the 1950s, the program has contributed to a substantial reduction in child mortality due to infectious diseases.2,3 Despite these successes, there is growing concern about issues related to possible side effects of vaccines, the feeling of unnecessary vaccination since the disease no longer exists, and the emergence of vaccine misinformation, contributing to a phenomenon called vaccine hesitancy.4–9 This phenomenon had a detrimental effect on vaccination uptake, weakening herd immunity and causing a resurgence of vaccine-preventable diseases.10–14 Vaccine hesitancy refers to uncertainty or indecision towards vaccination. Overall, hesitant individuals are placed on a continuum between complete acceptance and complete refusal of vaccines, despite the availability of immunization services.15,16 Therefore, it is crucial to identify vaccine hesitant parents before they reach a point of complete refusal, as their viewpoint can still be influenced by positive interventions. While extensive research on vaccine hesitancy has been widely studied in Western countries,17–19 there is limited local evidence on this matter. Hence, a valid measurement tool is deemed necessary to understand this issue in the local context.
Based on previous reviews, vaccine hesitancy has been measured using various tools, including heterogeneous assessment questions that vary in cut-off point, the Vaccine Hesitancy Scale (VHS), and the Parent Attitude about Childhood Vaccines (PACV). Aiming to standardise the assessment of vaccine hesitancy, the World Health Organization (WHO) has recommended the utilisation of VHS and emphasized the importance of validating it to ensure its applicability across various contexts. The VHS has been validated in numerous countries and has been translated into Spanish, Arabic, Turkish, Korean, and Chinese. Recently, a modified version of VHS has been made available in English and Spanish.

Given the recommendation of WHO for the utilisation of VHS, adapting this questionnaire at a local level would provide a more accurate basis for future analysis. Thus, the Modified Vaccine Hesitancy Scale (MVHS) was selected as a tool to identify vaccine hesitancy among parents in Malaysia. To the best of our knowledge, this MVHS has not been translated or validated in the Malay language. Therefore, our study aimed to translate the MVHS into Malay and subsequently validate the Malay version.

**MATERIALS AND METHOD**

**Study Design and Setting**

This was a cross-sectional study conducted over four months starting from April to July 2023. This study took place at government health clinics in ten districts of Kelantan. It consisted of two phases in which were Translation and Cultural Adaptation phase, and Validation and Reliability phase.

**Translation and Cultural Adaptation Phase**

A permission to translate the questionnaire into the Malay language from the original author was obtained beforehand. The process of translation and cultural adaptation process followed the established guideline. Forward translation were performed by two independent translators; a medical officer from the Maternal and Child Health Unit at the Ministry of Health (MOH) facility as translator one, and a teacher from the Language, Literacies and Translation Unit of Universiti Sains Malaysia (USM) as translator two. Both translators were fluent in Malay and English language. Any difficulty or confusing items, words, or sentences were highlighted. Then, a common translation was synthesised from both forward translations during the reconciliation process. In order to ensure the relevancy of the item, content validation was performed by a panel of experts consisting of three public health physicians, two family medicine specialists and one paediatrician. The experts agreed that all items were relevant to Malaysian parents. The reconciled version of the questionnaire was then proceeded for backward translated into English by another two independent translators. It was subsequently harmonized to improve any undue discrepancies. Overall, the translated version demonstrated satisfactory equivalences, and the reconciled version was used as pre-final MVHS-M during face validation.

A face validation or also known as cognitive debriefing was conducted using pre-final MVHS-M with ten respondents. The respondents were selected among the parents through purposive sampling during their visit to Gunong Health Clinics in Bachok district. Their selection criteria were based on the study criteria mentioned below. They were instructed to evaluate the understandability, interpretation, and cultural appropriateness of the translated questionnaire. Necessary amendments were made accordingly. Following this, pilot testing was carried out to identify any further shortcomings in the translated questionnaire and to refine the procedures related to its administration and data preparation for analysis. A total of 30 parents who fulfilled the same inclusion criteria and different respondents were ensured. The time required to answer all the questions ranged 15 to 20 minutes, which was considered acceptable.

**Validation and Reliability Phase**

The validation process was conducted with parents who met the same study criteria. A total of 270 parents were recruited from government health clinics in districts other than Bachok. A total of 62 respondents were invited to assess for stability by participating in a retest at seven-day intervals following the initial administration of the questionnaire.
Sample Size

The minimum recommended sample size for the validation phase was 200 samples.\textsuperscript{31,32} By considering the 20% non-response rate,\textsuperscript{33} the required sample size was determined to be 250. For test-retest, a sample size required of 62 respondents was calculated using Sample Size Calculator Version 2.0.\textsuperscript{34}

Sampling Method and Subject Recruitment

Respondents were recruited through a multistage random sampling method from the remaining nine districts. Initially, using simple random sampling, Kota Bharu, Pasir Mas and Pasir Puteh districts were selected. Then, nine government health clinics from the above districts were selected using the same sampling method. Despite the calculated sample size being 250, a total of 270 respondents were recruited after evenly distributing the number of participants for each clinic and rounding the figures. As a result, 30 respondents were recruited at each clinic.

Parents who aged over 18 years, had at least a child who aged $\leq 7$ years, and provided their consent were included in this study. However, non-Malaysian parents, parents with immunocompromised children, parents who attended the clinics solely for their child immunization and parents with cognitive impairment and intellectual disability were excluded. The sampling frame involved all parents who met the study criteria and attended government health clinics during study period. All participants were provided with a patient information sheet and required to provide written consent before participating. Using systematic random sampling, parents were selected at regular two-unit intervals at the registration counter of the clinics. They were instructed to fill out self-administered 9-item questionnaire of MVHS-M and sociodemographic proforma while waiting for their turn in the clinic. The participants were given 15 to 20 minutes to complete their answers, after which researcher collected the questionnaire and checked for completeness. For test-retest, only participants who had agreed during the initial session were contacted after seven days, and they were given a similar time frame to complete the answers again.

Research Tool

The original Vaccine Hesitancy Scale (VHS) was a self-administered questionnaire, developed by the SAGE Working Group on Vaccine Hesitancy. The development involved extensive literature reviews and discussion among experts.\textsuperscript{15} Following the development, the psychometric properties were not initially assessed, and were evaluated by Shapiro et al.\textsuperscript{23} They identified two subdomains; lack of confidence and risk were identified. However, prior validation studies showed inadequate psychometric properties, leading to development of a modified version of VHS.\textsuperscript{18,23,29} The Modified Vaccine Hesitancy Scale (MVHS) is a modified version that can be used to predict and identify vaccine hesitancy related to childhood vaccination.\textsuperscript{29} After some modification, the validated questionnaire was reduced from 10 items to nine items and maintain organized within two subdomains; lack of confidence and risk. The MVHS demonstrated good construct validity (RMSEA=0.09, CFI=0.96, TLI=0.94 and SRMR=0.04) and displayed good internal reliability with Cronbach’s alpha coefficients of 0.90 and 0.76, respectively.

In MVHS, instead of using a 5-point Likert scale as in the original VHS, each statement is measured using a 4-point Likert scale. The response options are “Strongly agree”, “Agree”, “Disagree” and “Strongly Disagree”. The “Neutral” option, scored as 3 in the original VHS was excluded in the MVHS to reduce the potential effect of social desirability bias.\textsuperscript{35} Numeric scores are still maintained as 1, 2, 4, or 5. Higher scores on MVHS indicate more hesitancy. The respondents were asked to choose the best response for each statement.

Statistical Analysis

Data entry was performed using IBM SPSS software version 26, followed by descriptive statistics to describe the numerical and categorical variables. Internal consistency reliability analyses using Cronbach’s alpha and the Intra-class Correlation Coefficient (ICC) were also conducted using the same software. The data was then transferred to Mplus version 8 for Confirmatory Factor Analysis (CFA) and estimation of composite reliability using Raykov’s rho.\textsuperscript{36} The sociodemographic
characteristics of the respondents were presented as descriptive statistics.

CFA was performed using a robust maximum likelihood estimator due to the lack of multivariate normality. Several fit indices were used to evaluate the model fitness including root mean square error of approximation (RMSEA; ≤0.08), Comparative Fit Index (CFI; ≥0.95), Tucker-Lewis Index (TLI; ≥0.95), and standardized root mean square residual (SRMR ≤0.08), based on established guideline. Items with standardised factor loading of 0.5 and above was as cut-off point in this study. Besides, the factor loading must be significant at α level <0.05. The initial model was evaluated using these fit indices. Then, the model specification was further considered by assessing the acceptability of the model, modification indices (MIs) and correlated item’s residual based on theoretical justification. To assess reliability, Raykov’s rho coefficient and Cronbach’s alpha were used to measure internal consistency, with a predetermined cut-off value of ≥0.7.

RESULTS
Sociodemographic Characteristics of Respondents.
The mean (SD) age of the respondents was 32.3 (SD 6.02). The majority were mothers (81.9%) and were not pregnant (51.6%) at the time of data collection. All participants were Malay, Muslim and had at least one child. Details of sociodemographic characteristics of respondents were displayed in Table I.

Confirmatory Factor Analysis of MVHS-M
The MVHS-M consists of nine items with two subdomains (lack of confidence and risk). In the initial measurement model as in Table II, most of the fit indices were acceptable, except for the TLI (RMSEA=0.07, SRMR=0.033, CFI=0.953, TLI=0.935). Since all items had factor loadings higher than 0.4 (Table III), no items were removed from the model. The initial model was further re-specified to improve fit indices. Researcher added a correlation between the residual for item C5 with C6 (Model-2) based on adequate theoretical support. Figure 1 shows a path diagram of MVHS-M which indicates present of correlated residual between C5 and C6. Model-2 demonstrated good fits with all fit indices falling within the recommended values.

Composite Reliability (CR) for Model-2 was calculated using Raykov’s method. The cut-off point considered in this study was >0.7, which is considered acceptable. The Average Variance Extracted (AVE) values were also provided in Table III. Internal consistency based on
Cronbach’s alpha ranged from satisfactory to good, with values ranging from 0.75 to 0.94. For stability testing, out of 62 distributed questionnaires, 51 respondents completed the questionnaire again on day seven after the initial administration (82.3% response rate). The Intra-class Correlation Coefficient (ICC) based on a two-way mixed effects model with the consistency option and average measures was 0.77 (95% CI 0.59, 0.87), which considered as good reliability over time.

**DISCUSSION**

Vaccine hesitancy is a global public health concern. Therefore, there is a need for validated scales with international comparability. Additionally, the experts recommended the validation of the VHS in different contexts and a modified version of VHS was developed, which produced better psychometric properties. This study aims to translate and validate the MVHS to assess vaccine hesitancy in the Malaysia population, specifically parents with children ≤7 years old. Hence, the current study contributes as the first report on the validation of MVHS in Malaysia. The findings revealed that the scale provided valid and reliable results for assessing vaccine hesitancy among parents with children ≤7 years old in government health clinics.

Based on Confirmatory Factor Analysis (CFA) (Table II), Model-2 exhibit a better fit compared to Model-1, leading to the selection of Model-2 as the best final model. Based on Hair et al. as expected when N>250 and observed variables <12, the cut-off values for CFI and TLI should be ≥0.95 and RMSEA <0.07, but SRMR may be biased. The fit indices in Model-2 were within the recommended values, indicating good fit for internal validity. Moreover, all fit indices in Model-2 showed better fit compared to the original modified version. In this study, Chi-square goodness-of-fit (χ²) was not reported due to its sensitivity to multivariate non-normality and sample size. However, normed chi-square (NC=χ²/df) was introduced to reduce the sensitivity of χ² to sample size. Despite, it was also not reported in this study as it does not play a major role in global fit testing. The standardised factor loadings for the MVHS-M presented in Table III ranged from 0.572 to 0.899, which were above the recommended cut-off point for factor loading (≥0.5) by previous literature. Thus, no items were
removed in the CFA model. In the current study, a correlated error item between C5 and C6, which were within the same factor was added after model re-specification based on theoretical justification as both items seem to measure the same aspect. However, this was not reported in the earlier version.29

Regarding reliability, the composite reliability (CR) of factors based on Raykov’s rho in this study ranged from 0.74 to 0.93, exceeding the suggested threshold of 0.7. Similarly, Cronbach’s alpha values ranged from 0.75 to 0.94. The findings suggested good reliability and accuracy of the MVHS-M in assessing parental vaccine hesitancy toward childhood vaccination. Therefore, if the assessment process was repeated, comparable results would be obtained.41 Previous version of VHS mostly utilised Cronbach’s alpha instead of the CR. The Cronbach’s alpha was found in the original VHS with values ranging from 0.64 to 0.92 among Canadian samples.23 This pattern of results aligns with other validation studies.18,19,22,29 Additionally, Average Variance Extracted (AVE) showed an acceptable value (≥0.5), indicating adequate convergent validity of the newly translated questionnaire.42 The MVHS-M also demonstrated stability and reliability over time, with a test-retest reliability demonstrated ICC of 0.77 after a 7-day interval, suggesting stability in assessing vaccine hesitancy among parents.

Comprehensive methodologies employed in the translation and cultural adaptation of the MVHS-M contributes positively impact to its clinical utility. These methodologies ensure that the newly translated version maintains the intended meaning of the original MVHS, utilised well-understood concepts and incorporates appropriate language for the Malaysian context. The application of MVHS-M is further enhanced since it was pre-tested, and piloted, and most importantly, the CFA showed a good model fit with good reliability and stability. Notably, it is interesting to note that the questionnaire consists of a concise set of nine items with straightforward and uncomplicated questions, making it suitable for self-administration. Thus, enhances the clinical utility of the MVHS-M.

One of the limitations of this study, as with previous VHS studies, that, is the mix of positively worded for “lack of confidence” items and negatively worded for “risk” items. This mixing of wording could potentially cause differences in responses based on question-wording rather than genuine underlying constructs within the items. Nevertheless, prior studies indicate that the utilization of scales that incorporate both positively and negatively worded items can result in confusion and tiredness among participants, perhaps failing to adequately address response bias.

Additionally, it should be noted that all respondents in this study were Malay ethnicity limiting the generalizability of the entire Malaysian population. Thus, generalizability should be done with caution. Furthermore, since the MVHS-M was translated into formal Malay, its usability is restricted to those who can read and understand the Malay language. Further study to translate and validate it to Tamil or Mandarin would enable its widespread use across the multi-racial population in Malaysia.

CONCLUSION

The MVHS-M demonstrates good construct validity and reliability, making it a useful tool for in assessing the magnitude of vaccine hesitancy among the parents regarding their child’s vaccinations. This tool enables the identification of high-risk parents, allowing for the development of targeted intervention and more effective strategies to address vaccine hesitancy.

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CONFLICT OF INTEREST

None

INSTITUTIONAL REVIEW

The study was conducted based on principles outlined in the Declaration of Helsinki. Ethical approval was granted from the Ethics Committee, Universiti Sains Malaysia (USM/JEPeM/KK/23010102) and Medical Research &
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REFERENCES


11. Kannan HK. 18 cases of Diphtheria, three deaths so far in Malaysia this year. New Straits Times. 2017 Aug 8;


34. Arifin WN. Sample size calculator (Version 2.0) [Internet]. 2017. Available from: http://wnarifin.github.io


