ORIGINAL ARTICLE

Psychometric Validation of Questionnaire Towards Awareness of Ototoxicity Risk Due to Solvent Exposure

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ABSTRACT

Introduction: Noise is a major risk factor for hearing problem; however, chemicals also contribute to the current prevalence of hearing problem worldwide. In many countries, industrial practices are performed without considering the possible ototoxic health consequences of solvents. Therefore, measuring the awareness level of ototoxicity risk has become a major concern. This study aims to validate a questionnaire to measure the awareness of ototoxicity risk among paint and coating manufacturing industriess. **Methods:** The questionnaire was adapted from Alnuman and Ghnimat (2019). The translation process in this study employed forward-only translations. The questionnaire was assessed in terms of its content and face validity before it was administered to 80 paint and coating manufacturing workers to determine the internal consistency reliability. **Results:** Content validation of this questionnaire showed an excellent content validity score with Content Validity Ratio (CVR) for each item and the mean score for all items included in the instruments; Content Validity Index (CVI) were both 1.0. Face validation resulted in an overall scale-level FVI of above 0.80, with an average index (S-FVI/Ave) for clarity and comprehension at 1.0 and 0.99, respectively. Meanwhile, the universal agreement index (S-FVI/UA) for clarity and comprehension of the questionnaire scale were both 0.90. Cronbach's alpha for internal consistency was excellent (0.82). **Conclusion:** The questionnaire to assess awareness level of ototoxicity risk from solvent exposure is valid and reliable. It demonstrates good psychometric properties. However, future research should look at additional types of validity and reliability, such as construct validity and test-retest reliability.
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INTRODUCTION

Regardless of noise exposure, research shows that exposure to specific substances known as ototoxicants can induce hearing loss or balance difficulties. These ototoxicants are defined as "any substance, including drugs or industrial chemicals, that is toxic to the auditory system" (1). Certain substances including insecticides, solvents, and medications can have a significant impact on how the ear works, cause hearing loss and affect the balance of the body (2). When employees are exposed to these substances while working in environments with high noise levels, the risk of hearing damage increases. Depending on the degree of noise, the ototoxicant dose, and the length of the exposure, this combination might cause temporary or permanent hearing loss.

Animal studies on ototoxicity have revealed mechanisms of action and audiologic consequences, whereas human observational and epidemiological investigations have found similar hazards and outcomes (3). Numerous studies have shown that 'solvent mixture', 'noise and solvent mixture' and 'toluene and noise' are ototoxic (4–9). A study found that there is a significant correlation between organic solvent and high-frequency hearing loss, with the estimated effect being greater than the audiometrically assessed (8). A recent study by Mohd Aris et al. (10) has explored the published literature on the detrimental effects of hearing from organic solvents exposure in a wide range of occupational setting in Asia. The key finding of this study indicated that the interaction of the ototoxic solvent with the noise may be both additive and synergistic.

An international supplier of industrial chemicals have indicated that paint and coating industries are among the industries that widely used solvents with approximately two million tons annually (11). In the paint and coating manufacturing industry, organic solvent is used as a raw solvent, in thinners and lacquers. The organic solvents are often used because they dry quickly when exposed to air, a characteristic that is desirable for most paint and coating applications. According to the Environmental Protection Agency (12) many solvents used by the paint and coating manufacturing industry are included in the Toxic Release Inventory (TRI) National Analysis 2017 chemical list which includes xylene (mixed isomers), toluene, methanol, n-butyl alcohol, and 1,2,4-trimethylbenzene due to the volatile characteristic; these solvents enter workers' bodies through inhalation and skin absorption.

In many countries, industrial practices are performed without considering the possible ototoxic health consequences of solvents. In order to substantiate this issue, solvent-induced hearing loss (SIHL) awareness questionnaire was developed and adapted from noise-induced hearing loss (NIHL) awareness questionnaire. To our knowledge, no local research or validated test has been established to investigate the awareness level of solvent-induced hearing loss. Therefore, this study aims to develop a valid and reliable tool to assess the awareness level of SIHL among paint and coating manufacturing workers. The content validity and face validity of the translated version of the adapted questionnaire were assessed. Secondly, this study also aims to assess the internal consistency reliability.

MATERIALS AND METHODS

Instruments

The questionnaire was adapted from Alnuman and Ghnimat (13). The questionnaire which consists of 18 questions was used by the authors to evaluate the knowledge of hearing health and the issues of NIHL. That study was aimed to build a baseline of knowledge that may be used in awareness-raising campaign.

On the other hand, this study consists of two (2) sections: section A (sociodemographic factors) and section B which assess the awareness level of hearing loss caused by exposure to solvents. The questionnaire requires 10 to 15 minutes to be completed. Section A gathers basic information of the workers which are the gender, age, level of education, position, work experience in the paint and coating manufacturing industry and average duration of exposure in a week. They were not included in the analysis to assess reliability and validity of the questionnaire. Section B consisted of 16 items which include five 2-point scale (yes/no) questions, five 3-point scale (big problem/not a big problem/not a problem at all) questions, and six extended questions. For yes or no questions, each positive response was allocated one score and each negative response was allocated zero score. The 3-scale questions were categorized into score one and zero based on the positive (one) and negative (zero) choice of answer. The purpose of the extended questions was to help the researcher gain a deeper understanding of the situation and their rationale based on their selected response. Below is the example of extended question.

Question 3: ***Have you ever read, heard or seen anything related to hearing problems from solvent exposure?*** (Yes/No (*if no, skip question 4*))

Question 4 (the extended question): ***Where have you read, heard, or seen something about hearing loss due to solvents exposure?***

The extended questions were not included in the analysis to assess reliability and validity of the questionnaire. Therefore, the maximum score for section B was ten.

Settings and procedures

This study was conducted in Selangor and Negeri Sembilan, Malaysia which involved two major stages; (i) Stage I: Translation and validation of instrument; and (ii) Stage II: Pilot testing. Phase I study was conducted between April 2020 and June 2020 and data collection for Phase II study was conducted between August 2020 and September 2020.

Expert panels reviewed the content of the items during the translation and content validation process to eliminate ambiguity and ensure that they were relevant and representative. The translated version was then pre-tested using face validation among the reference population to ensure that the items were clear and understandable (14). A pilot test was later conducted to determine the reliability of the finalised version of the questionnaire. Approval of human ethics was acquired from the Universiti Teknologi MARA (UiTM) Research Ethics Committee prior to conducting the study (Reference No.: 600-TNCPI(5/1/6)).

Stage I : Translation and Validation

The questionnaire was translated from English to Bahasa Malaysia (the national language of Malaysia) by the Malaysian Institute of Translation and Books (ITBM). ITBM provides expert translation services of the highest quality level. The benefit of using ITBM services is that questionnaire was not only translated, but also edited and proofread by the experts in the related field to verify that the language used is accurate and appropriate. The purpose of the translation was to retain the original meaning, style, and effect of the text while translating the actual meaning of the situation from English to Malay. The accuracy, clarity, and applicability of the translated instrument were all carefully addressed to obtain the highest possible translation quality. The Content Validity

Ratio (CVR) was calculated using Lawshe's approach for content validity analysis (15). Six experts consisting of academicians, public health physician, and chemical specialist from the Malaysia Institute of Higher Education and Malaysia's National Institute of Occupational Safety and Health (NIOSH) examined the questionnaire items. The experts rated items using a 3-point rating scale either as essential, useful, or not necessary. For each scale, a content validity index (CVI) was calculated by averaging the CVR for all the retained items of the scale (16,17). A CVI of more than 0.9 implies outstanding content validity (16).

Following the content validation, the purpose of the face validation was to verify the clarity of the instructions and words to see if there were any ambiguities or multiple interpretations of the item. Just like in the case of content validity, there are no guidelines for appointing respondents for face validity as long as there are at least ten respondents (18). The test subjects in this study were paint and coating manufacturingworkers. An online Google Form was used to invite a total of 28 workers to participate in the face validation task. They were asked to score the clarity and comprehension of each item on a four-point scale (1 = item is not clear/understandable; 2 = item is somewhat clear/understandable; 3 = item is quite clear/understandable and; 4 = item is highly clear/understandable). They were also asked to write down any comments or issues that needed to be changed. All the remarks given by the experts in content validation and respondents in face validation have been taken into consideration to produce the final version of SIHL questionnaire.

Stage II : Pilot Testing

A pilot test was conducted among 80 respondents. The self-administered Malay version questionnaire was distributed via an online survey using Google Form, where the link was sent to the workers. The study rationale was described in the form, and informed consent was gained before the respondents answered the questionnaire.

Data analysis

The content validity of the questionnaire was assessed using CVR and CVI. CVR is a statistical method for determining the validity of individual instrument items as determined by a panel of content experts. The CVI gives a numerical number to the overall mean CVRs of all the instrument items. The CVR and CVI can both give a quantitative assessment of a simulation evaluation instrument validity to researchers and users (19).

To assess the face validity of the questionnaire, the face validity index (FVI) was generated. Item-level face validity index (I-FVI) consisting of scale-level face validity index (S-FVI), averaging index (S-FVI/Ave), and universal agreement index (S-FVI/UA) were all included in the FVI calculation. The clarity and comprehension rating had to be transcoded as 1 (the scale of 3 or 4) or 0 (the scale of 1 or 2) before the FVI was calculated. In this study, the value of the CVI was adopted to interpret the value of the FVI, in which 80% and above was generally considered as an acceptable level of face validity (20). The FVI was calculated based on the following parameters (18):

i. I-FVI: The proportion of test respondents giving an item a clarity rating of 3 or 4.
ii. S-FVI/Ave: The average of the I-FVI scores for all the items on the scale or the average of proportion clarity and comprehension judged by all the raters.
iii. S-FVI/UA: "The proportion of items on the scale that achieve a clarity and comprehension scale of 3 or 4 by all raters. Universal agreement (UA) score is given as 1 when the item achieved 100% agreement by the raters, otherwise the UA score is given as 0."

The reliability analysis was performed using IBM Statistical Package for the Social Sciences (SPSS) version 28.0 software. Cronbach's alpha value above 0.7 was deemed to show an acceptable internal consistency reliability (21).

RESULT

Content validity

The Malay version of the questionnaire which consisted of 10 items was validated for the content by six experts. Table I shows the "essential" rating by the experts. Content validation of this questionnaire resulted in a CVR value of 1.0 for each item. Meanwhile, the mean score for all items included in the instruments, CVI is also 1.0. The content validity of the questionnaire has been determined to be acceptable. On the basis of expert comments and suggestions, modest changes have been made to each questionnaire item.

Table 1: "Essential" rating by 6 experts.

	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	Expert 6	Expert in agreement (n=6)	CVR
Item 1	x	x	x	x	x	x	6	1.0
Item 2	x	x	x	x	x	x	6	1.0
Item 3	x	x	x	x	x	x	6	1.0
Item 4	x	x	x	x	x	x	6	1.0
Item 5	x	x	x	x	x	x	6	1.0
Item 6	x	x	x	x	x	x	6	1.0
Item 7	x	x	x	x	x	x	6	1.0
Item 8	x	x	x	x	x	x	6	1.0
Item 9	x	x	x	x	x	x	6	1.0
Item 10	x	x	x	x	x	x	6	1.0
							CVI	1.0

Face validity

28 candidates were selected from the expected respondents. Table II and III shows the comprehension and clarity ratings on the item scale by 28 raters and calculation of face validity index. There were 9 items that achieved the I-FVI value of 1.0 for both clarity and comprehension rating. The face validation resulted in an overall scale-level FVI of above 0.80, with an average index (S-FVI/Ave) for clarity and comprehension at 1.0 and 0.99, respectively. Meanwhile, the universal agreement index (S-FVI/UA) for clarity and comprehension attained for the questionnaire scale were both 0.90. The questionnaire has achieved the satisfactory level of face validity.

Table II: The clarity ratings on the item scale by 28 workers.

Items	Raters in agreement (n=28)	I-FVI	UA
Item 1	27	0.96	0.0
Item 2	28	1.0	1.0
Item 3	28	1.0	1.0
Item 4	28	1.0	1.0
Item 5	28	1.0	1.0
Item 6	28	1.0	1.0
Item 7	28	1.0	1.0
Item 8	28	1.0	1.0
Item 9	28	1.0	1.0
Item 10	28	1.0	1.0
		S-FVI/Ave	1.0
		S-FVI/UA	0.90

Table III: The comprehension ratings on the item scale by 28 workers.

Items	Raters in agreement (n=28)	I-FVI	UA
Item 1	28	1.0	1.0
Item 2	25	0.89	0.0
Item 3	28	1.0	1.0
Item 4	28	1.0	1.0
Item 5	28	1.0	1.0
Item 6	28	1.0	1.0
Item 7	28	1.0	1.0
Item 8	28	1.0	1.0
Item 9	28	1.0	1.0
Item 10	28	1.0	1.0
		S-FVI/Ave	0.99
		S-FVI/UA	0.90

Pilot testing

A total of 80 paint manufacturing workers agreed to participate in this study. Among those, 74 (92.5%) were males and seven (7.5%) were females. Of the respondents, 76% were aged between 20 and 29 years old while 24% were aged 40 and above. Half of the respondents have Diploma/Competency Certificate (50%), Bachelor's degree (37.5%), SPM and below (11.3%) and 1.2% with Master's degree. Sixty percent of the respondents were from non-executive level, 32.5% from executive level and 7.5% were from managerial level. The majority of the respondents (48.8%) have more than 5 years of working experience. Most of the respondents (46.3%) were exposed to organic solvent 6 to 10 hours weekly. The profiles of the respondents can be seen in Table IV.

Table IV: Socio-demographic data of the respondents (n=80).

Characteristic	Frequency	Percentage (%)
Gender		
Male	74	92.5
Female	6	7.5
Age		
20-39 years old	61	76
40 years old and above	19	24
Academic status		
SPM and below	9	11.3
Diploma / Certificate	40	50
Degree	30	37.5
Master	1	1.2
Work Position		
Non-executive	48	60
Executive	26	32.5
Managerial level	6	7.5
Work experience		
Less than 1 year	11	13.8
1-5 years	30	37.5
More than 5 years	39	48.8
Duration of exposure		
Less than 1 hour	7	8.8
1-5 hours	33	41.3
6-10 hours	37	46.3
11-15 hour	0	0
16-20 hour	1	1.3
More than 20 hours	2	2.5

Internal consistency shown by the Cronbach's alpha coefficient was 0.77 when all the items were analysed. However, items 8 and 9 showed the values for Corrected-Item Total Correlation of less than 0.3, which were not acceptable. Therefore, items 8 and 9 were deleted. After deleting these two items, the total corrected correlation of each item was more than 0.3 and the Cronbach's alpha coefficient showed a value of 0.82 (Table V). The internal consistency of the questionnaire had achieved the acceptable level with high internal consistency based on Cronbach's alpha coefficient of over 0.7 (22)

Table V: Internal Consistency of the Finalized Items.

Items	Corrected Item-Total Correlation	Cronbach's alpha if item deleted	Cron-bach's alpha
Item 1	0.70	0.78	0.82
Item 2	0.59	0.80	
Item 3	0.73	0.78	
Item 4	0.50	0.81	
Item 5	0.48	0.81	
Item 6	0.68	0.78	
Item 7	0.34	0.83	
Item 10	0.49	0.81	

DISCUSSION

This research is the first work to evaluate the psychometric properties of the awareness towards ototoxicity risk among workers in paint and coating manufacturingindustry in Malaysia. This present study demonstrates the preliminary validity and reliability of the questionnaire.
The translation process was done by professional translators from an established translation service in Malaysia known as the Malaysian Institute of Translation & Books (ITBM). The questionnaire was also edited and proofread to ensure that the terminologies used are accurate and acceptable. The editor also pay attention to the linguistic style and relevant subtleties in line with the original material.

Once the translation process is done, a Content Evaluation Panel is formed. Six experts consisting of academicians, public health physician and chemical specialist were invited. According to Gilbert and Prion (19), the Content Evaluation Panel should be made up of people who are specialists in the topic under investigation. This panel should ideally include a variety of specialists (also known as subject matter experts) from diverse professional levels, with a panel of 5-10 experts as ideal. It is unlikely that more than ten specialists are required (23).

The CVR is an item statistic that is useful in rejection or retention of individual items and is internationally recognized as the method for establishing content validity (24). The CVI is the mean CVR for all the items included in the instrument (17). We are confident to include the items when all experts agree that it is "important." Items having a CVR of 0.78 or higher with three or more experts might be regarded as evidence for strong content validity (19,20). If an item fails to fulfil this condition, it is generally eliminated from the final instrument. In the current research, the CVR and CVI were both 1.00; thus indicating that all items were agreed to be "essential" in the SIHL questionnaire by all experts. Polit et al. (20) has recommended that for a scale to be judged as having excellent content validity, it would be composed of items that had I-CVIs of 0.78 or higher and an S-CVI/Ave of 0.90 or higher.

Consequently, an apparent understanding of the questionnaire can be provided using face validation process as it can measure the comprehension of the target population. The comments obtained from respondents during face validation were used to improve the questionnaire's clarity, layout, and presentation, as well as the projected time necessary to answer the questions (25). During the face validity process in this study, the raters were asked about the clarity and comprehension. Face validation resulted in an overall scale-level FVI of above 0.80, with an average index (S-FVI/Ave) rating of 1.00 for both clarity and comprehension. Meanwhile, a universal agreement index (S-FVI/UA) for clarity and comprehension of the questionnaire scale were attained at 0.90 and 0.99, respectively. The questionnaire has achieved the satisfactory level of face validity (18,26).

Internal consistency of the questionnaire was assessed by using Cronbach's Alpha Coefficient. The internal consistency of the questionnaire was found to be high as indicated by Cronbach's alpha values of more than 0.70. (21,27). The dependability of a summed scale was examined using an item-total correlation matrix, in which numerous items were summed to create the total scores. Items should be correlated with the total whereby the Corrected Item-Total Correlation should be greater than 0.3, therefore items with poor correlation may need to be deleted (28). Since the Corrected Item-Total Correlation for item 8 and item 9 were less than 0.3, both items were deleted to have a good internal consistency among the items. After eliminating both items, the final questionnaire was composed of 8 items, with the level of Corrected Item-Total correlations for all remaining items higher than 0.3 and a Cronbach's alpha of 0.82. These results pointed out that the questionnaire is a useful tool for measuring the awareness of solvent-induced hearing loss among paint and coating manufacturing workers.

The questionnaire was limited to three types of validity; content validity, face validity, and internal consistency; consequently, future research should look at additional types of validity and reliability, such as construct validity and test-retest reliability. The second limitation of the questionnaire is the absence of a cut-off score to identify low- and high-level awareness of solvent-

induced hearing loss. Hence, the limitations must be taken into consideration when designing future studies for further assessment of the measurement quality of the questionnaire. Despite these limitations, the study has a few implications as it validated the SIHL questionnaire for the use in the industrial population, specifically the paint and coating manufacturing industry in Malaysia. This would give valuable data to the researchers regarding the degree of hearing loss awareness due to solvent exposure. Data on the degree of awareness may also act as a needs analysis for developing an intervention guideline to manage ototoxicity risk among paint manufacturing workers.

CONCLUSION

The findings concluded that the SIHL questionnaire with eight items achieved excellent reliability in terms of content validity, face validity and internal consistency. Hence, it is a valid tool to assess the degree of solvent-induced hearing loss awareness among Malaysian paint and coating manufacturing workers.

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