

Assessment of Newborn Screening Programme for Congenital Hypothyroidism Implementation: Development and Validation of a Survey Instrument

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ABSTRACT

Background: The screening for congenital hypothyroidism (CH) aims for early diagnosis and appropriate treatment. This programme reportedly did not achieve its quality assurance performance in terms of percentage of patients seen for confirmation and percentage of confirmed cases that received treatment within 14 days. Immediate attention is needed to assess the behaviour of the programme implementer. Therefore, the present study aims to develop and validate a questionnaire based on the Theory of Planned Behaviour (TPB) and the Attitude, Social Norms, and Self-Efficacy (ASE) Model. **Methods:** Relevant document analysis and extensive review of the articles were performed in the process of domain identification and item generation. The newly developed instrument was evaluated by six panel experts using Content Validity Index (CVI) and distributed to six respondents for face validity. A cross-sectional study was piloted among 63 healthcare providers in a government hospital and two selected health clinics in Perak. Item analysis and reliability analysis were performed. **Results:** The initial item pool consisted of 45 items. The scale-level CVI (S-CVI) obtained based on the agreement of the panel experts was 0.96. As a result of the item analysis, eight items for the knowledge domain were dropped. As for the reliability analysis, one item for the attitude domain was dropped. In the end, the questionnaire consisted of 37 items. The Kuder-Richardson (KR20) value was 0.35, while Cronbach's alpha (CA) ranged from 0.720 to 0.893. **Conclusion:** The newly developed questionnaire has adequate validity and good internal reliability for quantifying providers' attitude, perceived behaviour control (PBC), knowledge, and behaviour intention.

Keywords: Attitude, Behavioural intention, Knowledge, Perceived behaviour control, Questionnaire development.

INTRODUCTION

Congenital hypothyroidism (CH) refers to deficiency of thyroid hormone, which is relatively a common cause of mental retardation, developmental delay, and growth disturbance that is preventable.^[1-3] Globally, it is estimated that the incidence of the disease is one in 2,000-4,000 live births.^[4-8] Studies have reported that in Malaysia, the incidence of CH occurs ranging from 1:3,666 to 1:1,170 live births.^[4-8] The screening for CH aims to ensure early diagnosis and appropriate treatment. However, in Malaysia, studies have reported that the programme did not achieve its quality assurance performance in terms of percentage of patients seen for confirmation and percentage of confirmed cases that received treatment within 14 days.^[9,12] Therefore, there is a need to improve on the programme implementation activities to ensure the

programme's success.

The programme's performance is influenced by the providers, clients or patients, and programme support environment. A study conducted among healthcare providers in Asian countries revealed that government prioritisation, cooperation of healthcare providers as well as public education and acceptance have contributed towards a successful screening programme.^[13] Before assessing others, it is important to assess the local healthcare providers in programme implementation. In view of this, immediate attention is needed to assess the behaviour of the programme implementers.

Many studies have applied the Theory of Planned Behaviour (TPB),^[14-35] and the Attitude, Social Norms, and Self Efficacy (ASE) Model in understanding the behavioural aspects of healthcare providers in programme implementation. Both models predict the occurrence of a specific behaviour,^[36-40] provided that the behaviour is intentional.^[41-45] TPB suggests that the intention of an individual to behave is determined by three main factors, namely attitude towards behaviour, subjective norms, and perceived behaviour control (PBC).^[41-42] The ASE Model suggests that apart from the three determinants of

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behavioural intention, factors such as knowledge, skills, and stimuli may play a role. As far as the researcher is concerned, there are no studies available pertaining to these in relation to the implementation of newborn screening programme. Most of the published studies are related to knowledge, attitude, and practice (KAP) in the context of newborn hearing screening programme.^[46-58] In view of this, there is a need to develop a new instrument in assessing the behaviour of healthcare providers focusing on the implementation of newborn screening for CH. Understanding these behaviours will be valuable in designing specific behaviour changing intervention strategies in order to improve the performance of the programme.

In developing a new study instrument, rigorous development processes are expected to ensure it is reliable and valid.^[59] This is essential to ensure the good quality of data that subsequently can be used in future research.^[60] Thus, the purpose of this study is to develop and validate a questionnaire based on TPB and ASE Model in order to assess the attitude, PBC, knowledge, and behavioural intention of healthcare providers.

MATERIALS AND METHODS

Development of the instrument

The development process involved several steps to ensure the newly developed instrument was valid and reliable.^[61] Relevant document analysis and extensive review of the articles on newborn screening,^[62-63] congenital hypothyroidism screening programme, and studies related to TPB and ASE Model were performed so that all relevant domains and subdomains for each construct can be identified. In this study, attitude refers to workers' feeling or opinion towards adherence to the implementation of the programme and its importance. PBC is defined as the overall evaluation of the degree to which workers believed that a screening programme for CH can be implemented as recommended; whereas behavioural intention refers to how likely workers intend to adhere to protocol in implementing the programme activities. For attitude, PBC, and behavioural intention, TPB was applied through a manual published specifically for health service researchers and existing studies, with domains or constructs based on TPB.^[64,65] Based on the information gathered, two subdomains were identified for the attitude domain, which are attitude towards the implementation of programme activities and the importance of the screening programme. As for the PBC domain, direct measurement was used and this could be achieved by assessing self-efficacy and controllability of participants. Generalised intention measurement was used to develop items for the behavioural intention domain.

For the knowledge domain, published studies evaluating healthcare providers in terms of

knowledge in implementing screening programmes for CH are extremely limited. However, the researcher found numerous studies published on hearing screening programmes for newborns. After a detailed assessment, four articles were finally selected as a guide in developing the knowledge items.^[47,53-55] In addition, the existing documents related to the programme implementation were referred in this process.^[62-63] To facilitate the researcher in identifying the full content domain, a table of specifications was used. In this study, the knowledge domain refers to the score of knowledge items related to the screening programme, symptoms, and consequences of CH. Based on the information gathered, three subdomains were identified, which are knowledge on the screening programme, symptoms, and complications of the disease. After the identification of domains and subdomains was completed, item generation and instrument construction were performed. The initial item pool consisted of 45 items.

Validation of the instrument

The development process was followed by the validation process based on a study conducted by Farizan et al.^[66]

Content validation

The newly developed instrument underwent a content validation process through a quantification process by a panel of experts (detailed review and assessment of CVI). In this process, a selected panel of experts evaluated the individual items as well as the entire instrument. The panel experts were identified among those who have vast experience, significant practical knowledge in this study field, and are up-to-date with the programme implementation activities. Each chosen expert was at least one of the following: (1) a Public Health Physician who is coordinating CH programmes; (2) a programme coordinator in a Paediatric Department; (3) a programme coordinator in a Pathology Department; (4) an academician in the public health related field (5) has published an article related to CH; and (6) a Family Medicine Specialist who has clinical expertise in the study field. Thus, a total of six experts were selected. The panel of experts selected was from district, state, and national levels. The panel consisted of two Public Health Physicians who were coordinating the programme (district and national levels), one Family Health senior lecturer from a public university, one Senior Paediatric Consultant from a state hospital, one Family Medicine Specialist inform a health clinic, and one Senior Science Officer from a laboratory of a state hospital. They were contacted by the researcher via a phone call and email to brief them regarding the study conceptualisations and item development for each construct.

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A set of 45-item questionnaires was distributed to each expert. Specific instruction was provided regarding the review questionnaire. Definitions for content domain were provided and keywords that the experts needed to address were highlighted to emphasise major review points. The experts were instructed to evaluate in terms of item content (representativeness) and item style (clarity). Subsequently, the entire instrument was evaluated by the experts for comprehensiveness to allow the researcher to revise the instrument if the items did not represent the content domain or missing domain areas were identified.

For the CVI assessment, the panel experts were required to evaluate each item using a 4-point scale introduced by Davis.^[67] : 1 = irrelevant, 2 = somewhat relevant, 3 = relevant and need correction, and 4 = very relevant. Subsequently, each item was categorised into two categories, namely irrelevant (items rated 1 and 2) and relevant (items rated 3 and 4). Based on these two categories, the values of item-level Content Validity Index (I-CVI) and S-CVI were calculated. A minimum I-CVI of 0.83 is required if 6 expert panels are used (61). For S-CVI of a newly developed instrument, the minimum acceptable value is 0.8.^[67]

Face validation

Once the content validity process was completed, the instrument was then distributed to six respondents involved in the programme implementation, but not included in the actual study, for face validity. This process was conducted to ensure the items developed were easy to understand. Sentence structure and grammar were also evaluated to ensure that the survey achieved the highest quality. Moreover, this process is very important to ascertain that the respondents are correct in their interpretation during the actual study. Based on the ratings and comments received from the respondents, the relevant items were reviewed.

Pilot study

A cross-sectional study was conducted among healthcare providers in a government hospital and two selected health clinics in the Perak state. The respondents comprised individuals who are involved in the programme implementation from receiving of samples until initiation of treatment. They were chosen in order to assess the validity and reliability of the newly developed instrument. For hospitals workers, they were from the Pathology and Paediatrics Departments. As for health clinics, it involved workers from the Maternal and Child Health (MCH) unit. Medical officers and nursing staff were recruited from the Paediatrics Department and health clinics, while for the Pathology Department, science officers and medical laboratory technicians (MLT) were recruited. Participants were selected using the purposive sampling method. Data

collection was carried out from September to October 2018. A brief description and purpose of the study was given to the participants. Written consent was taken from the participants who agreed to participate. All participants had to complete a set of questionnaire individually and submit it to the researcher or focal person in the organisation on the same day. Out of 70 sets of questionnaires that were distributed, 63 workers had answered. Subsequently, item analysis and reliability analysis were performed based on the result of this pilot study.

Difficulty Index and Discrimination Index

For the knowledge domain, item analysis was performed to calculate the items' difficulty index (DI) and discrimination index (RI). Both indexes ranged from 0 to 1.00. A smaller value of DI indicates a higher level of difficulty. Items with a DI value less than 0.2 need to be revised because they are considered too difficult. Meanwhile, items with an RI value less than 0.2 need to be revised as they cannot differentiate between knowledgeable and non-knowledgeable persons.^[68]

Reliability

For attitude, PBC, and behavioural intention domains, internal consistency reliability analysis and Cronbach's alpha (CA) values were applied. As the coefficient values are higher, the items in the questionnaire are considered more consistent to be used to measure the variables. The CA value of 0.65 and above is accepted as correct and consistent (60). As for the knowledge domain, reliability was measured using the Kuder-Richardson Formula 20 (KR20). KR20 values ranged from 0 to 1. High values indicate reliability, while values that are too high (greater than 0.90) are homogeneous.^[46]

Ethical consideration

The approval for this study was obtained from the following: (1) Research and Ethics Committee, Medical Faculty, National University of Malaysia; (2) Medical Research and Ethics Committee (MREC), Ministry of Health Malaysia; (3) Deputy State Health Director (Public Health) of Perak; (4) Deputy State Health Director (Medical) of Perak; (5) respective Hospital Directors in Perak; and (6) respective District Health Officers in Perak.

Data analysis

Few analyses were involved in this study. For content validity, the values of I-CVI and S-CVI were calculated. Percentage was used in the face validity process. For the construct validation of the knowledge domain, calculations of DI and RI were involved. As for internal consistency, CA and KR-20 values were calculated.

RESULTS

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Development of the instrument

The initial pool of items related was compiled based on the extensive literature search of previous studies' instruments. Apart from that, several items were adopted and modified to suit the study population. The initial item pool consisted of 45 items and were organised in an appropriate sequence. Items were prepared in a bilingual format (Malay and English). The attitude domain consisted of 15 items and ranged from (1) least important to (7) highly important. The PBC domain comprised six items and ranged from (1) strongly disagree to (7) strongly agree. As for the behavioural intention domain, it consisted of four items that measured compliance to timeframe, case management, guideline implementation, and cooperation and ranged from (1) least likely to (7) most likely. For the knowledge domain, there were 20 items with three responses, namely "Yes", "No", and "Unsure", in which correct answers were given one point, while incorrect and "Unsure" answers were given zero points.

Validation of the instrument

Content validation

All items for attitude, PBC, and behavioural intention domains had an I-CVI value of 1.0. However, some items were suggested for improvement in terms of words used and sequences. As a final draft, there were 15 items for the attitude domain, 6 items for the PBC domain, and 4 items for the behavioural intention domain. As for the knowledge domain, two items had an I-CVI value less than 0.83. Furthermore, there are three additional items suggested by the experts for further review. After the review, items with an I-CVI value less than 0.83 were dropped. All three additional items suggested were decided to be included in the content domain after being reviewed by the researchers. As a final draft, there were 21 items in the knowledge domain.

Overall, based on the I-CVI value of all the items, the S-CVI value was found to be 0.96. As a final draft, all 46 items constructed for the four domains (15 items for the attitude domain, 6 items for the PBC domain, 4 items for the behavioural intention domain, and 21 items for the knowledge domain) were reviewed by the same expert panel in 14 days as recommended by Davis.^[67] As a result, all 46 proposed items were finalised and agreed by the experts as a result of the content validity process.

Face validation

From the six participants involved in rating the instruments, more than 83% agreed that the content, structure, and formatting of the questionnaire were relevant and easy to understand. A majority of participants also agreed that the writing style, font size, and spacing of the text were appropriate. Based on the ratings and comments received from the respondents, the relevant items were reviewed with no additional or deleted item.

Difficulty Index and Discrimination Index

None of the items had a DI value less than 0.2. Out of 21 items of the knowledge domain, 13 items had a DI value more than 0.9 and out these 13 items, four of them had a DI value of 1.0 and were considered very easy. These four items were reviewed to examine relevance and appropriateness and were finally dropped after discussions with the experts. Meanwhile, the other nine items were retained. The remaining eight items (out of 21) with DI values ranging from 0.2 to 0.9 were also retained. As a result, 17 items were retained after the DI values were calculated. Based on these 17 items, nine items were found to have an RI value of less than 0.2 and were reviewed with the experts. As a result, four items were dropped because the RI value was too low. The other eight items with RI values within the range of 0.25-0.84 were retained. As a final result, 13 items of knowledge domain were retained after the RI values were calculated. For the remaining 13 items, the average value of DI was 0.86, which was very simple; whereas the average value of RI was 0.27, which was moderate in distinguishing knowledgeable and less knowledgeable respondents.

Reliability

For the attitude domain, out of the 15 items generated, the initial CA value was 0.68. After further discussion with the experts, the decision was made to drop one item with negative corrected item-total correlation in order to obtain a better CA value. The CA value of these 14 items was 0.893. For the PBC domain (six items) and behavioural intention domain (four items), the initial CA value was 0.78 and 0.72, respectively. For the knowledge domain, based on the average DI and RI values of the 13 items, the calculated KR20 value was 0.35. Finally, 14 items for the attitude domain, 6 items for the PBC domain, 4 items for the behavioural intention domain, and 13 items for the knowledge domain were agreed to be included in this instrument.

DISCUSSION

The development process involved domain identification based on the TPB model and resulted with the construction of the instrument to ensure that the instrument was properly developed. With regard to the content validation process, the value of S-CVI obtained based on the agreement of the panel experts was 0.96, indicating excellent content validity as suggested by previous studies.^[67-69] Additionally, based on the face validation process, the findings supported the present study's content validation process as the instrument was agreed to be relevant, easy to understand, and appropriate by a majority of the participants.

With regard to the pilot study conducted, validity of the knowledge domain was assessed using item analysis. The present study revealed that the

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knowledge items were very simple and moderate in distinguishing knowledgeable and less knowledgeable respondents based on the value of average DI (0.86) and RI (0.27), as suggested in a previous study.^[68] As for reliability analysis, the CA value for attitude, PBC, and behavioural intention domains indicated that the internal consistency was good. However, the knowledge domain's value was found to be low (KR20=0.35), which may need improvement as suggested by a previous study.^[66] In this study, although the value of KR20 was less than 0.6, the items were agreed by the experts as comprehensive enough to measure knowledge. Finally, 13 items for the knowledge domain were retained.

After rigorous development and validation processes, the new instrument demonstrated good reliability and excellent content validity in assessing the behaviour of healthcare providers. It is only applicable for the Perak state or other similar settings in terms of the implementation of programme activities. However, this instrument can still be used as a guide for other settings that may have some differences in their implementation. As for other countries that may not have this screening programme as their priority yet, consideration to establish a very good and structured programme is suggested, and this instrument is valuable for future evaluation purposes.

The involvement of the six panel experts in ensuring excellent content validity demonstrated that this instrument is comprehensive enough in determining the minimum requirement in terms of attitude, PBC, knowledge, and behavioural intention of healthcare providers in implementing the programme. Thus, strong attitude, high PBC, and knowledge score as well as full behavioural intention are required in order to implement the programme properly.

In this study, a small sample size was found to be the limitation. Hence, item analysis and reliability analysis are suggested to be performed on the data of the actual study to strengthen the validity and reliability of the items.

CONCLUSION

The development process, content validity, face validity, item analysis, and reliability analysis have demonstrated adequate validity and good internal reliability for quantifying healthcare providers' attitude, PBC, knowledge, and behavioural intention. Therefore, the survey instrument developed in this study is valuable in exploring and gaining better understanding in terms of the behaviour of healthcare providers in implementing the newborn screening programme for CH.

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