



Development, Validation and Pilot for Clinical Survey Research in Malaysia

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February 11, 2025

DEVELOPMENT, VALIDATION, AND PILOT FOR CLINICAL SURVEY RESEARCH IN MALAYSIA

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Abstract: Patient engagement concept combines patients' knowledge, capacity, and readiness to manage healthcare to promote a positive patient attitude. This concept encompasses 3 components including attributes, antecedence, and consequences which are then represented by personalization, access, commitment, and therapeutic alliances. Previous studies have resulted in the integration of patient engagement nationally. But, the utilization lacks the fundamental understanding of the theory and antecedence behind its implementation. **Objectives:** The objective of this study was to (1) to develop, validate three sets of questionnaires and perform a pilot testing to estimate the attributes contributing to patient engagement between personalization, access, commitment, and therapeutic alliances (PACT) among patients, doctors and administrators in Klang Valley **Methods:** There were three questionnaires developed for patients, doctors and administrators respectively. The sets of questions were assessed by psychometricians, researchers, and experts for review on the questions' construct suitability, content validity, and reliability. Then, a pilot survey was conducted involving 30 randomly selected and consented respondents from each sample group. Internal reliability score was calculated from data collected and a retest was done. **Conclusions:** The step-by-step method will aid in developing and implementing a successful patient engagement model to improve population health.

Keywords: engagement, patient, questionnaire development, validation, pilot

1. INTRODUCTION

In the fields of medicine, society, business, psychology, and behavior, survey-based studies are common. Questionnaires are frequently utilized in these studies as a research instrument to collect diverse participant data. To assess the effectiveness and scientific validity of any survey-based research, a well-designed questionnaire is essential. Proper planning is essential when creating a questionnaire to make sure that pertinent inquiries and items are taken into account in a manner that represents the particular constructs to be examined in a study. To guarantee accurate results, it is important to perform a questionnaire validation^[1]. A questionnaire must be designed, developed, and validated using a strict, methodical process. This article details the step-by-step development, validation, and pilot of the patient engagement study looking at three samples including patients, doctors, and administrators of healthcare. This study is unique, representing the first attempt to assess the concept of patient engagement within Malaysia's diverse and multiracial society in relation to our healthcare system. This article presents the main principal elements of patient engagement namely, personalization, access, commitment, and therapeutic alliances. It will describe the modified and newly developed questions catered specifically for our population^[2]. This is an important step to improve the understanding and success of any future patient engagement program.

2. METHODOLOGY

2.1 Questionnaire development

There were three sets of questionnaires developed for patients, doctors, and administrators respectively. Questionnaire development was based on Higgin's concept which comprised the 4 attributes of personalization, access, commitment, and therapeutic alliances (PACT)^[2]. A discussion was conducted among medical and social sciences experts to develop a set of suitable questions based on each component of PACT. These questions were newly created or modified from 2 major sources and their suitability for the multiracial setting was ensured:

- a. PCORI patient engagement survey (<http://pcori.org.Blog/Attitudes-Towards-CER>)^[3].
- b. The Quality of patient engagement and involvement in primary care: The King's Fund 2010 by S. Parsons et al^[4].

Dichotomous questions, multiple choice questions, important or rating scales, and close and open-ended questions were prepared for each component of PACT.

2.2 Pre-test

Face validation is essential for quantitative survey research to examine any concerns about the questionnaire such as unsuitable concepts and inappropriate language^[5]. During face validation of the questionnaire, the Experts' and Practitioners' perspectives were included in the questions. Experts' opinions were necessary to scrutinize and identify problematic issues during variable computing in advance, whereas practitioners' opinions are essential for the sensitivity of the items^[7]. The current research implies experts as academicians and statisticians and practitioners as social workers.

This study collected data in three stages: a pre-test, face validity, and then a pilot study to ensure question sensitivity to the respondents' language and cultures, corresponding to the variables^[8]. In the pre-test phase, the questionnaire was reviewed and examined by thirty external experts and practitioners to review the reliability of the questionnaire and to ensure that it measured accurate data. Pre-testing is carried out by five academics in the medical and statistics field in local universities. The researcher selected the experts and practitioners by a judgment sampling method considering their experience in treating patients in hospitals and expertise in social research and statistics. The method in which the researcher is involved "in the selection of the subjects who are most effective in the best position to utilize the information required" is referred to as judgment sampling^[8].

The researcher sent an email to experts and practitioners inviting them to participate in the survey, as well as requesting a review to identify any vague and inappropriate questions. The researcher made the survey available to the reviewers in English and Malay languages to ensure that the translated survey's chosen words were appropriate, and to allow reviewers to compare the items to the original English survey^[7]. The reviewers were asked to rate (1) the suitability of the wording, (2) the questionnaire organization, and (3) the clarity of the items. The researchers corrected the instrument according to the reviewers' feedback and modified it accordingly. The modified questionnaire was then introduced.

2.3 Validation (face and content validation)

Validity is known as the level of depiction precision of the theory of interest on a scale or series of assessments. An essential feature of validity is the level to which a measure reflects what it is designed to measure^[9]. The face and content validity classifications are used in this study. Face validity is referred to as the degree to which the instrument addresses and analyses key points of the research area, whereas content validity is referred as the degree to which information acquired via a certain instrument corresponds to the ideal substance to be estimated^[1]. During the face validation stage, the sets of questions were assessed by psychometrics for review on the questions' construct, validity, and reliability^[8]. The suitability of the questions for testing was then ensured. Content validation was performed by researchers and experts to determine the question representation and theme. The corrections and comments were then analyzed, and modifications were made prior to the pilot study.

2.4 Pilot test

A pilot study is essential for the development of the research's quality and efficiency. It's also done to evaluate the safety of interventions and recruitment potentials, examine the randomization and blinding process, enhance researchers' expertise with the study methodology and interventions, and provide sample size estimations^[5].

After validation was obtained, a pilot study was conducted. 100 patients, 100 doctors, and 50 administrators were randomly selected to fill in the questionnaire sheets as respondents. Each respondent was explained with regard to the nature of this pilot study. Consent is taken and demographics documented. The questionnaires are distributed using the printed and online system (Google forms) to ease the collection. For improvement purposes, the subjects were allowed to comment, clarify and reason regarding the questionnaire contents. Once completed, the questionnaires and comments were collected and analyzed. Changes are then made to the questionnaires based on the validation and reliability calculation taking into account the comments from participants. The internal reliability score was calculated from this data. Finally, a re-test was conducted to determine the understanding and reliability.

3. CONCLUSION

This article outlines a step-by-step process for developing and validating cross-sectional survey research questionnaires. The technique is meant to help researchers in creating a reliable questionnaire for their research in the clinical setting.

4. ACKNOWLEDGEMENT

The first acknowledgment of the writing of the paper. The second author refined the literature review and research framework of the questionnaire development, validation, and pilot study. Financial expenses were provided by the FRGS grant.

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