

# Development & Validation of a Bilingual Psychometric Instrument for Assessment of Knowledge, Attitude, Self-care Practice and Health-related Quality of Life (KAPQ-HF) among Heart Failure Patients

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## ABSTRACT

**Objective:** This study was conducted to develop and determine the validity and reliability of a bilingual psychometric instrument for assessment of knowledge, attitude, self-care practice and health-related quality of life (HRQoL) (KAPQ-HF) among Malaysian heart failure (HF) patients.

**Methods:** This was a cross-sectional, quantitative survey conducted in a Malaysian tertiary hospital involving a total of 325 HF patients. The self-administered questionnaire was first developed in Malay language through extensive literature reviews and was assessed for content and face validities, construct validity through item analysis and exploratory factor analysis (EFA), as well as reliability. The tool then underwent forward and back-translation into English and the harmonised English version was checked for reliability.

**Results:** Development of KAPQ-HF generated a total of 41 items and was reduced to 39 items after content and face validity testing, item analysis, factor analysis and reliability testing. Content validation showed that all the items in the questionnaires were essential, relevant and clear with content validity ratio (CVR) and content validity index (I-CVI) of 1.0 for all items. Face validation revealed that the questionnaire was fairly easy, relevant, suitable and acceptable. Factor analysis revealed the presence of simple structure with two factors in each domain with all items loading substantially only on 1 factor. KR-20 and Cronbach's alpha values which representing reliability of the questionnaire was excellent for HRQoL domain (0.901) and acceptable for knowledge, attitude and self-care practice (0.606, 0.654 and 0.671 respectively). The English version yielded KR-20 and Cronbach's alpha values of 0.607, 0.635, 0.708, and 0.893 for knowledge, attitude, self-care practice and quality of life respectively. The test-retest also showed that both versions of KAPQ-HF were reproducible (ICC > 0.7; P < 0.001).

**Conclusion:** The newly developed bilingual KAPQ-HF is valid and reliable and may be useful in assessing HF patients in ambulatory settings.

**Keywords:** Heart Failure, Knowledge, Attitude, Self-care Practice, Health-related Quality of Life.

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## INTRODUCTION

Heart failure (HF) affects approximately 26 million adults globally and its prevalence is worryingly increasing. [1] Prevalence data of HF in Southeast Asia is scarce but a single-center data from Singapore and Malaysia suggested prevalence of 4.5% and 6.7% respectively, which were higher than those reported in western countries. [2] Acute Decompensated Heart Failure Registry for Asia Pacific (ADHERE-AP), a web-based registry of 10,171 patients reported that Southeast Asia patients hospitalized with acute HF tend to be younger, presented with more severe clinical features, have longer lengths of stay and higher in-hospital mortality compared to those from other multicentre registries. [3] This highlights potential opportunities to improve outcomes, particularly through multidisciplinary initiatives. In Malaysia, such initiatives include the establishment of medication therapy adherence clinics (MTACs) by the Pharmaceutical Services Division, Ministry of Health Malaysia as part of its ambulatory pharmacy services. MTAC which is aimed at improving patients' adherence towards medications and general disease management through education involves close collaboration between pharmacists and medical practitioners and has now included HF in its program. [4]

In behavioural medicine, psychometric instruments allows measurement of individual's knowledge, ability, personality, and types of behaviours. [5] Although evaluation of HF therapy is usually based on objective measurable clinical outcomes, self-administered assessment is increasingly recognised as an important component of evaluation particularly the measurement of psychometric components such as knowledge, attitude, self-care practice and health-related quality of life (HRQoL). Association between knowledge and self-care practice, adherence to medications and disease management and clinical outcomes have been previously described. [6,7] Similarly, relationship between self-care practice and health related quality of life (HRQoL) have also been studied although not extensively. [8] Therefore, in order to optimise the success of educational programmes such as those conducted in MTACs, psychometric characteristics namely knowledge, attitude, self-care practice and HRQoL should be measured at baseline and progress monitored at intervals. However, psychometric tools to measure these domains have either poor validity methodologies, assessing only one domain or too lengthy, adding on a significant administrative burden if used in real clinical settings. [9] Thus, this study was conducted to develop and validate a single bilingual (English

and Malay) psychometric instrument to measure knowledge, attitude, self-care practice and HRQoL (KAPQ-HF) of HF patients that caters to the Malaysian demographics.

Specialist Clinic, Serdang Hospital during the study period. Patients with documented dementia or any other psychological disorders that prevents participation in the survey, illiteracy and those with significant language barrier were excluded from the study.

## METHODS

This was a cross-sectional study conducted at a referral tertiary public hospital involving adult patients (age  $\geq$  18 years) diagnosed with HF of any causes and NYHA classes undergoing follow-up at the Out-patient Cardiology

### Development of KAPQ-HF

The development of KAPQ-HF was performed through three-steps process - conceptualisation of the domains, items generation and instrument formation (Figure 1.0).

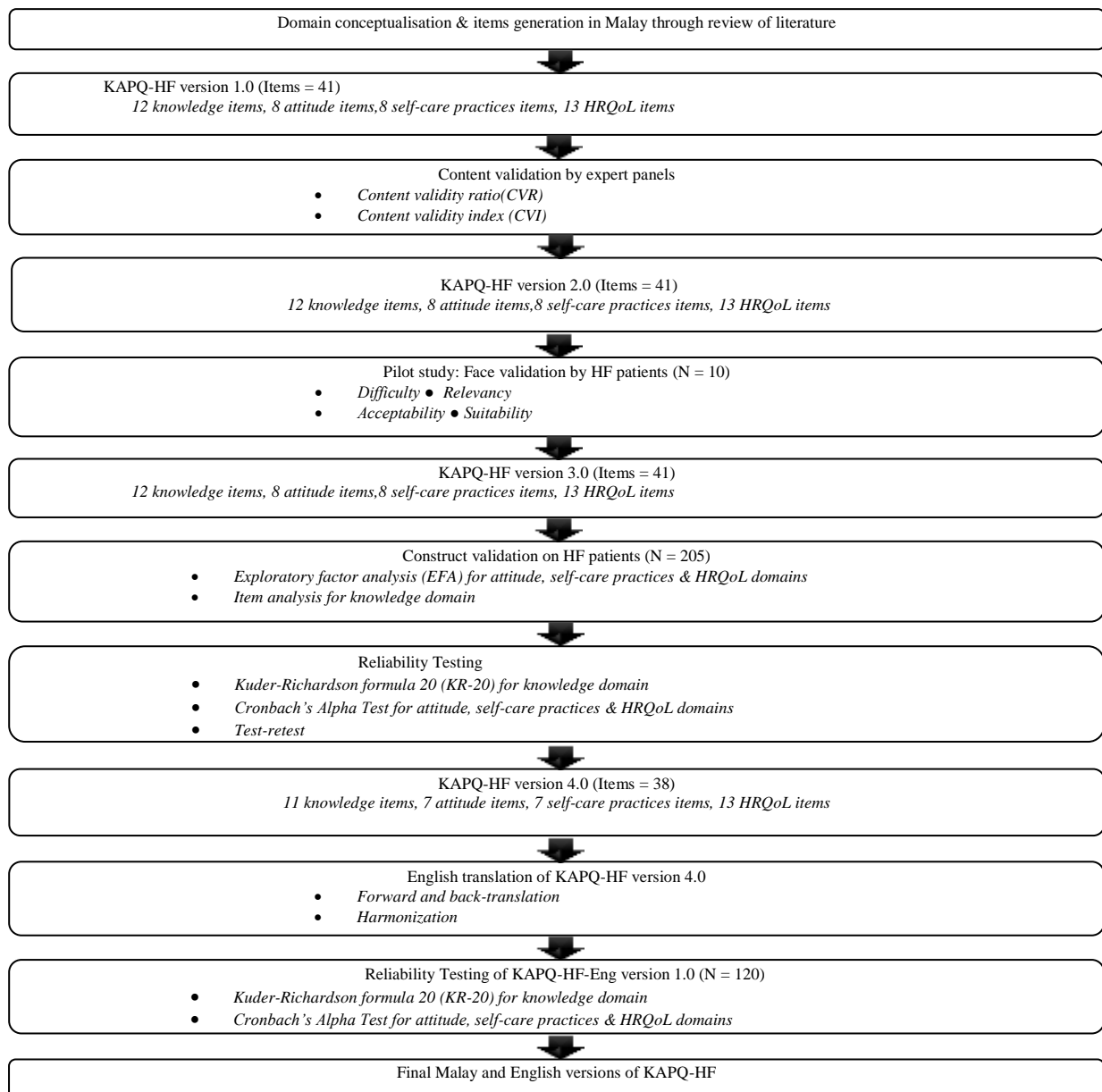


Figure 1.0: Research methodology

The items were structured using lay terms and the process involved extensive literature reviews of previously published research papers and clinical practice guidelines. KAPQ-HF was developed in Malay since it is the Malaysian national language and to tailor to the majority of the local population.

### Content Validity

Content validity was determined by three-panel experts comprising of a cardiology consultant and two coronary care unit pharmacists. The panels were asked to rate item suitability, relevance and clarity using a 3-point Likert Scale where 1 = not necessary, 2 = useful but not essential and 3 = essential. Content validity ratio (CVR) was then calculated

where  $CVR = (N_e - N/2)/(N/2)$ , in which the  $N_e$  is the number of panellists indicating "essential" and  $N$  is the total number of panellists. [10] Content validity index (CVI) was also calculated using experts' rating for each item based on the content relevance or representativeness of an instrument, on 4-point Likert scale ranging from 1 (not relevant or not representative) to 4 (extremely relevant or representative). For each item, item CVI (I-CVI) was calculated by counting the number of experts who rated the item as 3 or 4 and dividing that number by the total number of experts. Values range from 0 to 1 where I-CVI > 0.79 indicates item relevancy, 0.70 and 0.79 means the item needs revisions, and < 0.70 means the item needs to be eliminated. [10] The multi-rater modified kappa statistic ( $k^*$ ) was also calculated to account for possibility of chance agreement. Necessary modifications were made based on panel experts' feedbacks and KAPQ-HF version 2.0 was generated.

#### Face Validity

To ensure that the tool is of high acceptability among the intended target population, 10 HF patients were randomly recruited during pilot study and were asked to rate the difficulty level, relevancy, suitability and acceptability of self-administered questionnaire using a 3-point Likert Scale. The tool was then further modified based on subjects' general feedback to generate KAPQ-HF version 3.0.

#### Construct Validity

KAPQ-HF version 3.0 consisted of 41 items, therefore, 205 study subjects were recruited through convenient sampling using ratio of number of respondents to number of items of 5:1 in calculating the sample size. Previous studies recommended various ratio from 3:1 to 20:1 although five subjects for each item are adequate in most cases. [11] The self-administered questionnaire took approximately 15 – 20 minutes to be completed by study subjects.

Data on attitude, practice and HRQoL was evaluated for construct validity by performing exploratory factor analysis (EFA) as variables were measured at a scale level. [12] The knowledge domain, which was developed as multiple-choice questions produced dichotomous data and was excluded from EFA. Sampling adequacy was checked using Kaiser-Meyer-Olkin (KMO) Test and Bartlett's Test of Sphericity. Sample size is considered adequate when the KMO value is at least 0.60 and Bartlett's test shows statistical significance ( $P < 0.05$ ). [13] Factors were extracted using Principal Component Analysis (PCA) when Kaiser's criteria (eigenvalue > 1.0) and Scree Test graphical presentation were met. [11] Subsequently, factors were rotated using Oblimin factor solution to allow factors to be correlated. Only factors with factor loading of  $\geq 0.3$  were considered. Component correlation coefficient ( $r$ ) was used to determine discriminant validity where factors which are not conceptually related to each other would show low correlation ( $r < 0.5$ ).

Item analysis was performed for items in the knowledge domain to assess the difficulty level and whether the items can discriminate between subjects with good and poor knowledge. Item difficulty index (DiF-I) was calculated by

dividing number of correct responses to the knowledge items with total number of responses. [14] Items with DiF-I < 0.3 and > 0.7 were removed as they were considered as difficult and easy respectively. Total knowledge scores were then ranked and 33.3% of the subjects at the top and 33.3% at the bottom were analyzed. The ability of an item to differentiate between respondents of higher and lower abilities was assessed by discrimination index (Dis-I) where  $Dis-I = 2 \times [(H-L) / N]$ .  $H$  is the number of subjects in the upper group (33.3%) who responded correctly,  $L$  is the number of patients in the lower group (33.3%) who responded correctly and  $N$  is total number of the patients in both groups. [15] An item can better discern differences between the two groups if a higher Dis-I is obtained. Items were removed when  $Dis-I < 0.2$ .

#### Reliability

In this study, internal consistency for the dichotomous knowledge domain is tested using Kuder-Richardson formula 20 (KR-20) whereas attitude, self-care practice and HRQoL were assessed using Cronbach's Alpha. KR-20 and alpha ( $\alpha$ ) values of > 0.6 are considered acceptable for an exploratory research. [14,16] Stability of the tool was measured using test-retest involving 20 patients, with an interval of 2 – 4 weeks between the first and the second administrations of the questionnaire. Intra-class correlation coefficient (ICC) was measured, where ICC > 0.70 was taken as minimum standard for questionnaire reproducibility.

#### Translation of KAPQ-HF

The final KAPQ-HF questionnaire underwent forward and back-translation into English by 2 sets of independent bilingual translators. The English versions were then compared and harmonised. KAPQ-HF English version was then generated and distributed to 120 patients using a ratio of number of respondents to number of items of 3:1 due to limited number of subjects who were able to answer in English. Reliability of the English version was tested using Cronbach's Alpha test and test-retest of 20 subjects.

#### Ethical Approval

Ethical approval to conduct the study was received from the Malaysian Research Ethics Committee, Ministry of Health Malaysia prior to the commencement of the study (NMRR-17-2858-38901).

#### RESULTS

Development of KAPQ-HF version 1.0 yielded a total of 41 items with 12 items for knowledge domain, 8 items each for attitude and self-care practice and 13 items for HRQoL domains. Items in the knowledge domain were structured in the form of multiple-choice questions with one mark awarded for every correct answer and zero mark for incorrect or 'I don't know' answers. Items in the attitude domain were assessed using 5-point Likert scale with 1 denoting 'strongly disagree', 2 for 'disagree', 3 for 'neutral', 4 for 'agree' and 5 for 'strongly agree'. For the self-care practice domain, 4-point Likert scale was used with 0 for 'never', 1 for 'seldom', 2 for 'frequent' and 3 for 'always'. Items D1 – 12 in the HRQoL domain were assessed using 6-point Likert

Scale with 0 for 'no', 1 for 'very mild', 2 for 'mild' 3 for 'average' 4 for 'severe' and 5 for 'very severe'. Since the total number of items for this domain were not similar between Muslim and non-Muslim subjects, the total scoring system was then converted to percentage. Item D13 employed a visual analogue scale (VAS) to self-assess level of health was reported as mean (SD). The scoring was reversed for all negative statements.

Content validation by 3 content experts produced a calculated CVR and I-CVI of 1.0 for all items indicating that all the items in the questionnaires were essential, relevant and clear. Modified kappa values ( $k^*$ ) were also 1.0 for all items which implied that expert agreement did not occur by chance. Therefore, none of the items were deleted at this stage although some minor amendments were made based on the comments made by the experts, yielding KAPQ-HF version 2.0. Similarly, face validation found that the questionnaire was fairly easy, relevant, suitable and acceptable. Therefore, no items were removed although based on the comments received, answer options for knowledge domain were reduced with questions having "yes", "no", and "I don't know" options. These changes generated KAPQ-HF version 3.0.

Item analysis revealed that item A6 which asked on the maximum allowable total daily salt intake was found to be difficult and unable to discriminate between respondents that have good and poor knowledge, hence, was considered for removal (DiF-I 0.195; Dis-I 0.104) (Table 1.0). The remaining of the items achieved DiF-I between 0.3 – 0.7 and DI > 0.2 which translated as ideal difficulty level and able to discriminate between those with good and poor knowledge.

EFA of the attitude, self-care practice and HRQoL domains revealed presence of 3-factor solutions with initial Eigenvalues > 1.0. However, inspection of the scree plots revealed a clean break after the second factor for all three domains. Therefore, only two factors explaining cumulative variance of 44.8 %, 44.9 % and 59.4 % for attitude, self-care practice and HRQoL domains respectively were retained for further investigation. Oblimin rotation with Kaiser normalisation revealed the presence of simple structure with both factors in each domain and all items loading substantially only on 1 factor (Table 2.0). As shown in Table 2.0, factor loading for item C7 which measures attitude on participation in discussion with doctor during clinic appointment was < 0.3. For the attitude domain, factor 1 represents attitude towards self-care and signs & symptoms monitoring while factor 2 represents attitude towards disease burden & complications. For the self-care practice domain, factor 1 consists of items assessing on self-practice related to exercise, salt and medication intake while factor 2 consists of items assessing on self-care practice of fluid limitation and monitoring. For the HRQoL domain, factor 1 items measure HRQoL on mental, social and financial burdens of HF while factor 2 items assess HRQoL on daily activities. Structure coefficients supported the correlation between variables and the factors, while component correlation coefficient ( $r$ ) showed that the 2 factors within each domain were only weakly correlated with each other.

Table 3.0 illustrates the internal consistency and stability of KAPQ-HF version 3.0 and KAPQ-HF English version. Item

A6 from knowledge domain was removed to improve KR-20 value from 0.569 to 0.606 while removal of item B5 from the attitude domain improved Cronbach's alpha coefficient from 0.600 to 0.654. Removal of item C7 increased Cronbach's alpha coefficient from 0.666 to 0.671. For HRQoL domain, Cronbach alpha coefficient was excellent at 0.901. In test-retest, intraclass correlation coefficient (ICC) for all domains were > 0.9 indicating excellent stability/reproducibility ( $P < 0.0001$ ). With the removal of item A6, B5 and C7, KAPQ-HF version 4.0 which contains a final total number of items of 38 was generated.

Table 1.0: Item difficulty index (DiF-I) and discrimination index (Dis-I) for knowledge domain of KAPQ-HF version 3.0 (N = 205)

Item	Description of item	DiF-I	Dis-I
A1	Definition of HF	0.310	0.478
A2	Symptoms of HF	0.325	0.612
A3	Role of salt in HF	0.525	0.254
A4	Pharmacotherapy: function of diuretics	0.350	0.567
A5	Pharmacotherapy: function of ACE inhibitors	0.300	0.239
A6	Recommended total daily salt intake	0.195*	0.104*
A7	Recommended total daily fluid intake	0.470	0.418
A8	Weight monitoring in HF	0.325	0.224
A9	Symptoms of acute HF	0.325	0.642
A10	Complication of HF	0.415	0.493
A11	BP control in HF	0.420	0.358
A12	Cholesterol level control in HF	0.595	0.224

\*Item A6 was considered for removal after item analysis

Table 2.0: EFA of items in the attitude, self-care practice and HRQoL domains of KAPQ-HF version 3.0 using PCA with Oblimin rotation (N = 205)

Item	Description of item	Pattern coefficient (factor loading)		Structure coefficient		Component correlation coefficient, r
		Factor 1	Factor 2	Factor 1	Factor 2	
B1	Attitude towards weight monitoring	0.518	0.295	0.518	0.296	0.002
B2	Attitude towards daily fluid restriction	0.729	-0.167	0.728	-0.166	
B3	Attitude towards high-salt food	0.674	-0.241	0.673	-0.240	
B4	Attitude towards medical attention-seeking	0.737	-0.075	0.737	-0.074	
B7	Attitude towards prognosis of HF	0.280	0.675	0.281	0.675	
B5	Attitude towards medication-taking when BP is normal	0.166	0.422	0.165	-0.421	
B6	Attitude towards prognosis of HF	0.164	0.780	0.165	0.781	
B8	Attitude towards burden of medication-taking	-0.002	0.482	-0.001	0.482	
C3	Avoidance of high-salt food	0.477	0.257	0.563	0.417	0.335
C5	Medication-taking practice	0.704	0.056	0.723	0.292	
C6	Medication-storing practice	0.875	-0.328	0.765	-0.034	
C8	Physical exercise	0.599	0.133	0.644	0.334	
C1	Daily weight monitoring	-0.135	0.790	0.129	0.744	
C2	Daily fluid intake	0.230	0.547	0.414	0.624	
C4	Symptoms monitoring	0.140	0.617	0.347	0.664	
C7	Participation in discussion with doctor	0.282*	0.132*	0.326	0.226	
D5	Physical aspect: religious activities	0.774	-0.195	0.832	-0.427	-0.299
D6	Physical aspect: dependency on others	0.755	-0.177	0.808	-0.403	
D7	Emotional aspect: need to be alone	0.830	0.077	0.807	-0.172	
D8	Emotional aspect: restrictions in dietary intake and movement	0.687	-0.149	0.731	-0.355	
D9	Emotional aspect: public appearance	0.785	-0.131	0.824	-0.366	
D10	Financial burden	0.532	-0.040	0.544	-0.199	
D11	Specific religious aspect (muslim): daily prayers	0.714	-0.101	0.744	-0.315	
D12	Specific religious aspect (muslim): fasting	0.753	0.054	0.736	-0.171	
D13	Visual analogue scale (VAS): health status	0.370	0.338	0.269	0.227	
D1	Physical aspect: house chores	-0.195	0.701	-0.405	0.760	
D2	Physical aspect: task-induced symptoms	-0.423	0.612	-0.606	0.739	
D3	Physical aspect: stair-climbing	-0.220	0.735	-0.440	0.801	
D4	Physical aspect: mobility	-0.483	0.637	-0.673	0.781	

\*Item C7 was considered for removal after EFA

Table 3.0: Reliability testing of KAPQ-HF version 3.0 (N = 205) and KAPQ-HF English version 1.0 (N = 120)

Domain	KR-20	Cronbach's Alpha coefficient	Intraclass correlation coefficient (ICC)	95% CI	P-value
KAPQ-HF Malay version 3.0					
Knowledge	0.606 <sup>i</sup>	-	0.944	0.854 – 0.978	<0.0001
Attitude	-	0.654 <sup>ii</sup>	0.941	0.833 – 0.978	<0.0001
Self-care Practice	-	0.671 <sup>iii</sup>	0.962	0.905 – 0.985	<0.0001
HRQoL	-	0.901	0.989	0.971 – 0.996	<0.0001
KAPQ-HF English version 1.0					
Knowledge	0.607	-	0.918	0.794 – 0.968	<0.0001

Attitude	-	0.635	0.796	0.485 – 0.919	0.001
Self-care Practice	-	0.708	0.952	0.878 – 0.981	<0.0001
HRQoL	-	0.893	0.994	0.985 – 0.998	<0.0001

i after the removal of item A6

ii after the removal of item B5

iii after the removal of item C7

The English version of KAPQ-HF was successfully translated based on KAPQ-HF version 4.0, back-translated and harmonised, resulting in 38-item KAPQ-HF-Eng version 1.0. The KR-20 and Cronbach's Alpha values for knowledge, attitude, self-care practice and HRQoL were 0.607, 0.635, 0.708 and 0.893 respectively. Intraclass correlation coefficient (ICC) for knowledge, self-care practice and HRQoL were > 0.9 indicating excellent stability ( $P < 0.0001$ ) whereas a value of 0.76 obtained for the attitude domain indicates acceptable stability ( $P = 0.001$ ) (Table 3.0).

The final versions of KAPQ-HF in both Malay and English therefore consisted of 38 items with a possible minimum score of 0 point and a possible maximum score of 167 points.

## DISCUSSION

HF is a complex clinical syndrome that require multidisciplinary approaches including structured and individualised management and education programs that regularly assess psychometric characteristics to ensure optimal clinical outcomes. In this study, a single, bilingual, self-administered tool to measure multi-dimensional psychometric characteristics that is relatively quick to administer and easy to analyse has been made available. Assessment of knowledge, attitude, self-care practice and HRQoL among Malaysian HF population is essential to assist healthcare providers in identifying areas to be addressed in disease management programs.

A well-designed questionnaire is concise, easily-understood and strongly resonant with the respondents whilst allowing research objectives to be answered.<sup>[17]</sup> Close-ended questions in the form of multiple choices with dichotomous options were employed for the knowledge domain in this study to easily quantify knowledge on various topics while scaled items were used for attitude, self-care practice and HRQoL domains to quantify the degree to which the respondents felt about the topics covered. Although some controversies existed on to whether a neutral point should be offered, removal of this option would force the respondents to choose a less-representative response that may lead to respondent irritation and increase non-response bias.<sup>[18]</sup> 'I don't know' option was also included in the factual knowledge domain to eliminate 'forcing' respondents in make a choice by guessing, which can introduce bias.<sup>[19]</sup>

A questionnaire should also contain sufficient items to measure the construct of interest, but not be lengthy that respondents experience fatigue or loss of motivation in completing the questionnaire<sup>20</sup>. Care was taken to ensure that the number of items were minimised to allow patients to be able to complete KAPQ-HF within 15 – 20 minutes. In

this way, recruitment of respondents can be maximised, and respondents' interest and focus can be retained until completion of the questionnaire. However, this approach limits the topics to be measured. For example, in the self-care practice domain, items focused more on self-care maintenance such as medication-taking behaviour, self-care monitoring such as symptoms recognition and less emphasis was given for self-care management such as treatment actions during symptomatic episodes.

A validated instrument is essential in ensuring clinically useful data.<sup>[21]</sup> Therefore, the complex and vigorous validation processes that KAPQ-HF was subjected to is well-justified. Content and face validities exploit on how well the idea of a theoretical construct is represented in an operational measure. Content validity deserves a rigorous assessment process as the obtained information from this process are invaluable for the quality of a newly developed instrument.<sup>[22]</sup> Through content and face validations and item analysis, this study demonstrated that KAPQ-HF were essential, relevant, of fair difficulty level and clear. Comprehensibility of items by the target group is important, especially when the instrument is developed for a specific population such as HF patients.

In this study, oblique instead of orthogonal rotation was utilised during EFA to permit factors to be correlated in order to produce more accurate results in researches involving human behaviours where factors are unlikely to be completely independent of each other.<sup>[13]</sup> This was proven when most factor loadings were > 0.3 when Oblimin rotation was used. Factor loading played an important role in item deletion as it represents the correlation between the items and its respective factors.<sup>[23]</sup>

Although KR-20 and Cronbach's Alpha values of > 0.7 – 0.9 are generally preferred and indicate high reliability, values > 0.6 is sufficient to indicate acceptable reliability especially in exploratory studies. Cronbach's Alpha values are also expected to be low when small scales are used.<sup>[16]</sup> In this study, smaller scales were used for the self-care practice and attitude domains, as compared to 6-point Likert scale used for the HRQoL domain. These differences in scale size largely explained the lower Cronbach's Alpha values measured in the attitude and self-care practice domains (0.654 and 0.671 respectively) and a higher value of 0.901 measured in the HRQoL domain.

Test-retest reliability measures the stability of the scores of a stable construct obtained from the same person on two or more separate occasions.<sup>[24]</sup> The time period between the repeated administrations should be long enough to prevent recall but short enough to ensure that clinical change has not occurred. In this study, the time period allocated was between 2 – 4 weeks in parallel with patients' attendance to the hospital either for follow-up services or collection of

repeat prescriptions. In the past, Pearson product moment correlation coefficient was often used to measure test-retest reliability but it is now discouraged as it cannot detect systematic error as opposed to ICC. [25] Reproducibility of KAPQ-HF was proven when ICC values for all domains were highly significant.

## CONCLUSION

HF has been associated with high mortality and a major course of hospitalisation which warrant continuous improvement to the disease management. This study was the first to develop and validate a single multi-dimensional, bilingual instrument to assess knowledge, attitude, self-care practice and HRQoL among HF patients particularly in the Malaysian context. A single validated instrument that can be used at the point of care in real clinical settings such as in ambulatory HF clinics is highly desirable to establish baseline and monitor progress of the patients. KAPQ-HF is content, face and construct validated, reliable and reproducible.

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## CONFLICT OF INTEREST

None to declare.

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