

# Improving the Reporting Quality of Instrument Cross-Cultural Adaptation: the IRICA Statement

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## Research Article

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# Abstract

**Background:** To achieve a consensus on the reporting checklists for instrument Cross-Cultural Adaptation (CCA) research.

**Methods:** Firstly, we clarified the research rationality with literature review and established the preliminary checklist pool based on information extracting. Then, using the focus group and expert interview, we optimized the checklists. Finally, the international Delphi surveys were conducted to evaluate the agreement degree, importance and familiarity of the checklists. In data analysis, 21 indicators were included for quantitative assessments, accompanied with group discussions.

**Results:** A total of 61 articles was included for rational analysis and 70 items were extracted to establish the checklist pool. After focus group and experts interview research, a checklist draft contains 25 items was put forward. In the three-rounds of international Delphi surveys, 14(70.00%), 11(68.75%) and 11(68.75%) questionnaires were completed. Basing on the quantitative analysis and group discussions, 1, 1 and 9 items were deleted, added and modified. Finally, we formed the checklist for Improving the Reporting quality of Instrument cross-cultural adaptation (IRICA) which contains 24 items subhead under 6 sections: Title and structured summary, Rationale and Objective, Authorization, Participants Criteria, Forward Translations, Forward Synthesis, Backward Translations, Backward Synthesis, Experts Qualitative Review, Pilot Testing, Field Testing, Statistical methods, Participants, Series Instruments, Main results, Other analyses, Summary of evidence, Comparison of instruments, Limitations, Copyright owner interaction, Application attentions, Conclusions, Appendix, Funding.

**Conclusions:** The IRICA statement can be used to guide users to report instrument CCA research in a standard manner, and assist to evaluate the reporting quality and study design.

## Background

Increasingly, quality of life (QOL) is becoming an important component of clinical health assessment, especially for chronic diseases, psychological and mental related diseases, and so on. In its preliminary concept, QOL is 'an individual's perception of their position in life in the context of the [culture] and value systems in which they live, and in relation to their goals, expectations, standards and concerns', defined by WHO in 1993[1]. Of those, 'culture' is emphasized as the first inter latent factor which influence the QOL, which formed an important branch of QOL research, instruments Cross-Cultural Adaptation(CCA) or translation, during the last decade. Tremendous progress has been made in developing CCA instruments, for example, there are 160 translations for SF-36 Health Survey, 51 translations for World Health Organization Quality of Life assessment instrument, etc., listed in ePROVIDE™ platform. And, many CCA research guidelines were proposed by many famous academic organizations and institutions [2-4].

Despite notable efforts to promote and facilitate the conduction of QOL instruments CCA researches, scant attention has been paid to its reporting. Nowadays, reporting guideline has been regarded as critical to enhance the quality of research design, text writing and evidences accumulation, such as the the CONSORT (CONsolidated Standards of Reporting Trials)[5], the STROBE (STrengthening the Reporting of OBServational studies in Epidemiology)[6], and the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses)[7], etc. However, except the COSMIN (COnsensus-based Standards for the selection of health Measurement INstruments)[8] and the PROQOLID (Preferred Reporting Items for Patient-Reported Outcome Instrument Development)[9], much few consensus focused on the reporting of QOL and patient-reported outcome (PRO) research, particularly for instruments CCA.

To generate recommendations that address these areas of need, we employed a modified Delphi process, which uses multiple rounds of evaluation to gauge and facilitate consensus among a group of experts on a particular topic[10-11]. The Delphi technique was chosen because it is recognized as an optimal method for consensus building, with the key strengths that it avoids the effects of overly vocal and dominant persons or the tendency to conform to a particular viewpoint, and can help to identify where agreement does and does not exist[12-13]. Referring to the 'Guidance for Developers of Health Research Reporting Guidelines'[14] and the CREDES (Guidance on Conducting and REporting DELphi Studies)[15], this study aims to achieve a consensus on the reporting checklists for instruments CCA research that would act as a guidance for developers and users.

## Methods

### *Identify the need for guideline*

To clarify whether there were reporting guidance for instruments CCA research, literature reviews in the PubMed and IEEEExplore were performed. Meanwhile, A catalogue of reporting guidelines for health research (Updated tables, 7 May 2014)[16] and secondary references were also examined. The exact search strategies were listed in Appendix 1. If an article proposed 1) the guidance, consensus, or criteria of reporting or writing; or 2) comprehensive research procedure for instruments CCA or translation research, it was included in the next step.

### *Establish and optimize the checklists pool*

After all eligible articles were reviewed, information related to the reporting or writing for instruments CCA were extracted and coded. Then, identical and duplicate codes were deleted, and similar codes with overlapping content were consolidated. Based on these key codes, researchers immersed the composite reaction in a single item, classified items into general topics and summarized them into concise checklists pool. Then, using a semi-structured questionnaire, the research group discussed the checklists content, purpose, redundancy and clarity one by one until a high degree of agreement was reached ( $\geq 80\%$  participants agree). With an introduction to describe its aims and usage methods, the optimized questionnaires for instruments CCA were formed with Chinese and English language. Finally, the research advisers (Author 2, Author 4) evaluated the consistency of each researcher's comments and endorsed the selection of checklists for Delphi survey.

### ***Identify Expert panel***

We identified the experts who have quality of life research, methodology, statistics, academic, and clinical backgrounds. The initial experts list was generated by profiling the council members of the Association for Chinese Quality of Life (WACQOL), the International Society for Quality of Life Research Translation & Cultural Adaptation Special Interest Group and the Patient-Reported Outcomes Methods Group of Cochrane Collaboration with relevant expertise. Their name, title, institution, corresponding address and E-mail were collected. Experts with middle or higher (preferred) title grade, and two or more (preferred) backgrounds were primary identified for international Delphi survey. The geographical, reputation, and convenience were also considered. This study was approved by the Research Ethics Committees in First Affiliated Hospital of Guangzhou University of Chinese Medicine.

### ***Conduct a Delphi survey***

E-mails containing the link to web-based survey and WORD format survey were distributed to all experts in the panel. And, the statements on informed consent for all experts were provided clearly in the second-round optimized checklists pool and corresponding survey questionnaire as 'This survey is free. However, to show your distinctive contribution to the study and our heartfelt appreciation, we will present your name, institution, et al. in the Experts Lists and Acknowledgment in our dissertation, articles and research summary for National Administration reviews, etc.. But if you DO NOT AGREE to present your personal information, please sign here: (If you 'agree', please ignore this question)' (Appendix 4 and 5), and in the third-round optimized checklists pool and corresponding survey questionnaire as 'Do you agree to list your name and institution in the acknowledgement in the articles to express our great appreciation for your contributions? 1=Agree ( ); 2=Disagree ( )' (Appendix 6 and 7). All the experts were weekly reminded with Email to complete the survey within one month until feedback was received. The survey in each round all contains the invitation, introduction and example, checklists and scores, open-ended questions, and socio-demographic questionnaire. Of those, experts answered the Agreement Degree for the checklists on a 3-Grade scale (Disagreement, Partial agreement, Total agreement), and the Familiarity and Importance on a 10-Likert scale (higher score indicates higher Familiarity and more importance), and could also choose to add free text comments for all open-ended questions. In the first round, we provided the questionnaire with blank answer and reference; in the later rounds, the experts were given the questionnaires presented with the mean and standard deviation of the group's previous responses. After the questionnaires returned in each round, data were scrutinized and transcribed by Author 3 into SPSS software and quantitative analyzed by Author 1. This was followed by research group discussions, which gave participants the opportunity to collectively discuss emerging conclusions and recommendations. Correspondingly, these checklists were repeat amended on the basis of the mixed evidences and terminated once data saturated. With the attainment of consensus, the final version for improving the reporting quality of instrument CCA (IRICA) was generated.

### ***Data Analysis***

Following 21 indicators in 5 data sets in- and between-rounds were included for quantitative analysis. 1) Experts' demographic and general information, including the age, gender, title, country/state, background, recall rate, and familiarity with checklists; 2) Level of central tendency for checklists, including the means, median, mode, sum, and totally agreement percentage; 3) Level of dispersion for checklists, including the standard deviation, percentiles 25, percentiles 75, and inter-quartile range (IQR); 4) Harmonious degree, including the coefficient of variation (CV), Kendall's coefficient of concordance, and the Cronbach's  $\alpha$  of three domains (Agreement Degree, Importance, Familiarity) and total questionnaire; 5) Between-rounds variation, including the absolute difference in CV, and F-ratio. The free comments for open-ended questions in group discussions and Delphi surveys were summarized for qualitative reviews[17-19].

The checklist in each round of survey was 1) included directly without change if its Agreement Degree mean  $\geq 2.00$ , Importance mean  $\geq 8$ , totally agreement percentage  $\geq 70\%$ , both CVs  $\leq 0.3$ , and no free comments involved; 2) deleted if its Agreement Degree mean  $\leq 1.50$ , Importance mean  $\leq 5$ , totally agreement percentage  $\leq 30\%$ , any of CVs  $> 0.8$ , or many comments on deletion occurs; 3) modified in other situations. Data simultaneous met the following criteria means saturation and the Delphi survey terminated: IQR  $\leq 1$ , F-ratio  $\leq 1$ , the absolute difference in CV decreased with round increased, P Value of Kendall's W  $< 0.05$ , and the total Cronbach's  $\alpha > 0.7$ . All analysis were conducted with SPSS (version 17.0).

## **Results**

### **Literature review and rational analysis**

A total of 926 articles in PubMed, 95 in IEEEExplore, 1 in A catalogue of reporting guidelines for health research, and 34 secondary references were respective reviewed. According to the inclusion criteria, 19 guidelines[2-4, 20-35], 17 strict literature reviews[36-52], 13 important experts opinions[53-65] and 12 high quality CCA researches[66-77] were included for analysis. Many studies excluded on the basis of the abstract described the guidance for clinical disease management, partial steps in CCA research, or studies no related to our aims, and so on. Of the 61 studies included in the study, almost all focused on the comprehensive research procedure or methods for instruments CCA or translation. So, to our best knowledge, little attention was given to the research reporting. As a result, the development of a consensus for instrument CCA reporting has been proposed by the research group as a solution to this problem.

### **Establish and optimize the checklists pool**

Accompanied by the rational analysis, the information related to the reporting or writing for instrument CCA research were also extracted and coded. After winnowing and binning, 70 items in 9 sections were included first in the checklists pool (Version 1, in Appendix 2). Then, the research group discussed the checklists one by one till a high degree of agreement was reached (July 2014, in Guangzhou), and an English version has 39 items and corresponding description was identified (Version 2, in Appendix 3). Then, the research advisers (Author 2, Author 4) evaluated the consistency of each researcher's comment in expert interviews (August 2014, in Guangzhou), and endorsed the selection of checklists for 26 items (Version 3, in Appendix 4). Two bilingual researchers (Author 3, Author 5) translated it into Chinese version until a high consensus was reached (Version 3, Chinese version in Appendix 5). Eight researchers

engaged in the pilot test and discussed the item's comprehensive, operability, content, purpose, redundancy, clarity, etc. (February 2015, in Guangzhou), and renewed the questionnaire to 25 recommendation items with expert's opinions on the Agreement Degree, Importance, Familiarity and Other Advice, plus one open-ended question 'Do you have any comments on the modifications to the checklist, and in particular any difficulties you faced in giving an answer?', and a short socio-demographic questionnaire (Version 4, Chinese version in Appendix 6, and English version in Appendix 7). These surveys were transformed to web online version for international Delphi survey.

#### Identify Expert panel and Conduct a Delphi survey

We recruited a total of 20 experts on the panel and conducted 3 rounds surveys. 20, 16 and 16 questionnaires were respective distributed in each round and 14(70.00%), 11(68.75%) and 11(68.75%) questionnaires were completed and returned. The key characteristics of those who completed the Delphi survey are detailed in Table 1. The more exact socio-demographic characters and academic backgrounds were provided with Appendix 8. All the experts agreed to participate in the research and list their name and institution in the articles.

Table 1  
The socio-demographic characters and research background of experts participated in the international Delphi survey in three rounds.

Socio-demographic Characteristics	Round 1 (n = 14)	Round 2 (n = 11)	Round 3 (n = 11)	$\chi^2/F$	P Value
<b>Recall Rate</b>	14/20(70.00%)	11/16(68.75%)	11/16(68.75%)	0.009	0.995
<b>Age</b>	46.83 ± 9.04	48.60 ± 6.74	50.73 ± 6.74	1.366	0.505
<b>Gender</b>					
Male	10(71.40%)	9(81.80%)	7(63.60%)	0.937	0.626
Female	4(28.60)	2(18.20%)	4(36.40%)		
<b>Title grade</b>					
Senior grade	9(64.30%)	9(81.80%)	11(100.00%)	8.433	0.077
Vice Senior grade	3(21.40%)	2(18.20%)	0(0.00%)		
Middle grade	2(14.30%)	0(0.00%)	0(0.00%)		
<b>Country, State</b>	11(78.57)	9(81.82%)	9(81.82%)	16.605	0.924
<b>Research Background</b>					
Quality of Life Researcher	9(64.30%)	6(54.50%)	6(54.50%)	0.336	0.845
Methodologist	6(42.90%)	5(45.50%)	5(45.50%)	0.023	0.988
Statistician	7(50.00%)	7(63.60%)	5(45.50%)	0.809	0.667
Academic Scholar	11(78.60%)	10(90.90%)	10(90.90%)	1.060	0.589
Clinician	5(35.70%)	3(27.30%)	5(45.50%)	0.794	0.672
<b>Totally Familiarity</b>	9.43 ± 0.61	9.64 ± 0.35	9.80 ± 0.14	1.672	0.207

#### Round 1

In round 1, 5 items met the modify criteria (item 13b, 17, 21, 22, 24, totally agreement percentage < 70% but > 30%, and item 22's importance mean < 8 but > 5), and 1 item met the deletion criteria (item 11, totally agreement percentage < 30%, and importance mean < 8 but > 5) based on the agreement degree analysis (Table 2) and importance analysis (Table 3). The familiarity analysis results were shown in Appendix 9. Meanwhile, 20 items received 35 advice (item 1b, 3, 11, 21 with 3 advice; item 2a, 2b, 4, 6, 13b, 15, 16 with 2 advice; and item 1a, 8, 12, 13a, 14, 19, 20, 22, 25 with 1 advice) and 6 open comments. In group discussion, the researchers deleted the item 11 (*"Provide the research procedure and missions of international harmonization."*) because of its poor total agreement percentage (28.57%), importance mean (7.46) and CV (0.327), and 3 advice for delete. Besides, according to the expert's advice, we divided item 3 (*"Provide the translation agreement and ethics permission."*) to item 3a and item 3b (added), and modified 7 items. Though the modifications of item 13b, 17, 22 and 24 were required by the qualitative analysis and/or expert's advice, we only modified the items descriptions instead of stems because there were no adequate necessities based on acquired evidences.

Table 2  
The Agreement Degree analysis of 25 items for the reporting of Cross-cultural Ad

Items	Mean			Median			Mode			Sum			Totally Agreement Percentage			Std. Deviation (%)		
	R1	R2	R3	R1	R2	R3	R1	R2	R3	R1	R2	R3	R1	R2	R3	R1	R2	R3
Item1a	3.00	2.91	2.73	3.00	3.00	3.00	3.00	3.00	3.00	42.00	32.00	30.00	100.00	90.91	72.73	0.00	0.30	
Item1b	2.86	3.00	3.00	3.00	3.00	3.00	3.00	3.00	3.00	40.00	33.00	33.00	85.71	100.00	100.00	0.36	0.00	
Item2a	2.86	2.91	3.00	3.00	3.00	3.00	3.00	3.00	3.00	40.00	32.00	33.00	92.86	90.91	100.00	0.54	0.30	
Item2b	2.86	2.91	3.00	3.00	3.00	3.00	3.00	3.00	3.00	40.00	32.00	33.00	85.71	90.91	100.00	0.36	0.30	
Item3a	2.79	3.00	2.91	3.00	3.00	3.00	3.00	3.00	3.00	39.00	33.00	32.00	78.57	100.00	90.91	0.43	0.00	
Item3b	NI	2.82	2.82	NI	3.00	3.00	NI	3.00	3.00	NI	31.00	31.00	NI	81.82	81.82	NI	0.41	
Item4	2.79	2.91	2.91	3.00	3.00	3.00	3.00	3.00	3.00	39.00	32.00	32.00	78.57	90.91	90.91	0.43	0.30	
Item5	2.93	2.91	2.91	3.00	3.00	3.00	3.00	3.00	3.00	41.00	32.00	32.00	92.86	90.91	90.91	0.27	0.30	
Item6	2.71	2.82	2.73	3.00	3.00	3.00	3.00	3.00	3.00	38.00	31.00	30.00	71.43	81.82	72.73	0.47	0.41	
Item7	2.93	2.82	2.73	3.00	3.00	3.00	3.00	3.00	3.00	41.00	31.00	30.00	92.86	81.82	72.73	0.27	0.41	
Item8	2.79	2.91	2.82	3.00	3.00	3.00	3.00	3.00	3.00	39.00	32.00	31.00	78.57	90.91	81.82	0.43	0.30	
Item9	2.79	2.45	2.73	3.00	2.00	3.00	3.00	2.00	3.00	39.00	27.00	30.00	78.57	45.45	72.73	0.43	0.52	
Item10	3.00	2.91	2.82	3.00	3.00	3.00	3.00	3.00	3.00	42.00	32.00	31.00	100.00	90.91	81.82	0.00	0.30	
Item11	2.21	NI	NI	2.00	NI	NI	2.00	NI	NI	31.00	NI	NI	28.57	NI	NI	0.58	NI	
Item12	3.00	3.00	2.91	3.00	3.00	3.00	3.00	3.00	3.00	42.00	33.00	32.00	100.00	100.00	90.91	0.00	0.00	
Item13a	3.00	2.91	3.00	3.00	3.00	3.00	3.00	3.00	3.00	42.00	32.00	33.00	100.00	90.91	100.00	0.00	0.30	
Item13b	2.64	2.82	2.91	3.00	3.00	3.00	3.00	3.00	3.00	37.00	31.00	32.00	64.29	81.82	90.91	0.50	0.41	
Item14	2.79	2.73	2.64	3.00	3.00	3.00	3.00	3.00	3.00	39.00	30.00	29.00	78.57	72.73	63.64	0.43	0.47	
Item15	2.71	2.64	3.00	3.00	3.00	3.00	3.00	3.00	3.00	38.00	29.00	33.00	71.43	63.64	100.00	0.47	0.51	
Item16	2.93	2.91	2.91	3.00	3.00	3.00	3.00	3.00	3.00	41.00	32.00	32.00	92.86	90.91	90.91	0.27	0.30	
Item17	2.64	2.55	2.45	3.00	3.00	2.00	3.00	3.00	2.00	37.00	28.00	27.00	64.29	54.55	45.45	0.50	0.52	
Item18	2.79	3.00	2.82	3.00	3.00	3.00	3.00	3.00	3.00	39.00	33.00	31.00	78.57	100.00	81.82	0.43	0.00	
Item19	2.86	3.00	2.82	3.00	3.00	3.00	3.00	3.00	3.00	40.00	33.00	31.00	85.71	100.00	81.82	0.36	0.00	
Item20	2.93	3.00	2.91	3.00	3.00	3.00	3.00	3.00	3.00	41.00	33.00	32.00	92.86	100.00	90.91	0.27	0.00	
Item21	2.57	2.55	2.55	3.00	3.00	3.00	3.00	3.00	3.00	36.00	28.00	28.00	64.29	54.55	54.55	0.65	0.52	
Item22	2.43	2.55	2.45	2.50	3.00	2.00	3.00	3.00	2.00	34.00	28.00	27.00	50.00	54.55	45.45	0.65	0.52	
Item23	2.79	2.73	2.82	3.00	3.00	3.00	3.00	3.00	3.00	39.00	30.00	31.00	78.57	72.73	81.82	0.43	0.47	
Item24	2.57	2.73	2.55	3.00	3.00	3.00	3.00	3.00	3.00	36.00	30.00	28.00	57.14	72.73	54.55	0.51	0.47	
Item25	2.86	2.64	2.73	3.00	3.00	3.00	3.00	3.00	3.00	40.00	29.00	30.00	85.71	63.64	72.73	0.36	0.51	

\*R1, Round 1 of Delphi survey; R2, Round 2 of Delphi survey; R3, Round 3 of Delphi survey; NI, No Information; NR, No caculate Result.

Table 3

The Importance analysis of 25 items for the reporting of Cross-cultural Adaptation research

Items	Mean			Median			Mode			Sum			Std. Deviation (SD)			Percentiles 25		
	R1	R2	R3	R1	R2	R3	R1	R2	R3	R1	R2	R3	R1	R2	R3	R1	R2	R3
Item1a	9.92	9.79	9.95	10.00	10.00	10.00	10.00	10.00	10.00	129	98	80	0.28	0.42	0.09	10.00	9.68	9.85
Item1b	9.69	9.93	9.96	10.00	10.00	10.00	10.00	10.00	10.00	126	99	80	0.48	0.16	0.07	9.00	9.95	9.93
Item2a	9.76	9.96	9.96	10.00	10.00	10.00	10.00	10.00	10.00	127	100	80	0.44	0.08	0.07	9.45	9.95	9.93
Item2b	9.88	9.90	9.98	10.00	10.00	10.00	10.00	10.00	10.00	128	99	80	0.30	0.32	0.05	9.95	10.00	9.93
Item3a	9.46	9.69	9.68	10.00	9.95	9.85	10.00	10.00	10.00	123	97	77	0.78	0.42	0.44	9.00	9.38	9.18
Item3b	NI	9.67	9.55	NI	9.95	9.70	NI	10.00	9.00	NI	97	76	NI	0.43	0.47	NI	9.23	9.00
Item4	9.28	9.45	9.58	9.60	9.25	9.75	10.00	9.00	10.00	121	95	77	0.84	0.50	0.52	8.50	9.00	9.13
Item5	9.65	9.87	9.95	10.00	10.00	10.00	10.00	10.00	10.00	126	99	80	0.63	0.32	0.09	9.25	9.93	9.85
Item6	8.81	9.53	9.59	9.00	9.65	9.60	10.00	10.00	10.00	115	95	77	1.52	0.50	0.42	8.00	9.00	9.13
Item7	9.69	9.75	9.69	10.00	10.00	9.90	10.00	10.00	10.00	126	98	78	0.60	0.43	0.44	9.50	9.38	9.18
Item8	9.32	9.65	9.66	10.00	10.00	9.70	10.00	10.00	10.00	121	97	77	1.09	0.47	0.32	9.00	9.00	9.53
Item9	8.96	8.60	9.45	9.00	9.00	9.75	10.00	9.00	10.00	117	86	76	1.30	1.58	0.65	8.25	7.75	8.73
Item10	9.69	9.76	9.76	10.00	10.00	9.85	10.00	10.00	10.00	126	98	78	0.63	0.63	0.34	9.50	9.90	9.65
Item11	7.46	NI	NI	8.00	NI	NI	8.00	NI	NI	97	NI	NI	2.44	NI	NI	5.50	NI	NI
Item12	9.85	9.79	9.93	10.00	10.00	10.00	10.00	10.00	10.00	128	98	79	0.38	0.42	0.10	10.00	9.68	9.80
Item13a	9.92	9.80	9.98	10.00	10.00	10.00	10.00	10.00	10.00	129	98	80	0.28	0.42	0.05	10.00	9.75	9.93
Item13b	9.08	9.48	9.88	10.00	9.75	9.95	10.00	10.00	10.00	118	95	79	1.50	0.67	0.16	7.50	9.00	9.73
Item14	9.55	9.65	9.50	10.00	9.65	9.65	10.00	10.00	9.00	124	97	76	0.75	0.37	0.43	9.25	9.43	9.00
Item15	9.02	9.40	9.73	9.00	9.00	9.80	10.00	9.00	10.00	117	94	78	1.18	0.52	0.34	8.50	9.00	9.55
Item16	9.58	9.91	9.89	10.00	10.00	10.00	10.00	10.00	10.00	125	99	79	1.12	0.19	0.19	9.75	9.90	9.75
Item17	8.73	8.39	8.74	9.00	8.45	8.95	10.00	8.00	9.00	114	84	70	1.56	1.57	0.53	7.25	7.75	8.13
Item18	9.08	9.59	9.65	10.00	9.80	9.85	10.00	10.00	10.00	118	96	77	1.75	0.47	0.43	8.00	9.00	9.13
Item19	9.27	9.65	9.74	10.00	9.75	9.85	10.00	10.00	10.00	121	97	78	1.42	0.41	0.34	8.75	9.38	9.60
Item20	9.15	9.40	9.90	10.00	9.50	10.00	10.00	10.00	10.00	119	94	79	1.41	0.66	0.18	8.00	9.00	9.83
Item21	8.45	8.75	8.88	9.50	8.50	9.00	10.00	8.00	9.00	110	88	71	2.22	1.09	0.45	7.65	8.00	8.60
Item22	7.62	8.75	8.96	9.00	8.25	9.00	10.00	8.00	9.00	99	88	72	3.10	0.92	0.26	6.00	8.00	8.77
Item23	8.85	9.15	9.48	10.00	9.25	9.55	10.00	10.00	10.00	115	92	76	1.57	0.88	0.52	7.00	8.00	9.10
Item24	8.69	8.80	8.99	10.00	9.00	9.00	10.00	8.00	8.00	113	88	72	1.89	1.03	0.72	7.50	8.00	8.20
Item25	8.61	8.90	9.21	10.00	8.75	9.05	10.00	8.00	9.00	112	89	74	2.40	0.84	0.67	7.00	8.00	8.93

\*R1, Round 1 of Delphi survey; R2, Round 2 of Delphi survey; R3, Round 3 of Delphi survey; NI, No Information; NR, No calculate Result.

As for rounds terminating analysis, although the IQR of total agreement percentage, *P* Value of Kendall's *W* and total Cronbach's  $\alpha$  all met the terminate criteria (Table 4), the IQR of importance was not so satisfied (15 items did not met). In addition, a total of 41 free comments also indicated it needs further research (Table 5).

Table 4

The Rounds-terminate analysis for the international Delphi survey for the reporting of Cross-cultural Adaptation research.

Rounds	Kendall's coefficient of concordance			Cronbach's $\alpha$			
	$\chi^2$	Kendall's <i>W</i>	<i>P</i> Value	Total	Agreement Degree	Importance	Familiarity
Round 1	724.068	0.793	< 0.001	0.954	0.802	0.910	0.961
Round 2	695.650	0.838	< 0.001	0.956	0.870	0.910	0.926
Round 3	563.500	0.849	< 0.001	0.907	0.778	0.858	0.881

Table 5

The Rounds-terminate analysis for the international Delphi survey for the reporting of Cross-cultural Adaptation research.

Survey Beginning	Items Analysis	Rounds Terminate Analysis	Survey Ending
Round 1: 6 sections, 25 items	<b>Statistical Analysis:</b> <b>Delete:</b> 1 item <b>Modify:</b> 5 items <b>Expert's Advice:</b> 20 items received 35 advice and 6 open comments <b>Group Qualitative Discussion:</b> <b>Delete:</b> 1 factors, 1 items (item 11) <b>Modify:</b> 7 items (item 1a, 2a, 2b, 3a, 14, 15, 21) <b>Add:</b> 1 items (item 3b)	<b>Statistical Analysis:</b> <b>Yes:</b> IQR of agreement degree, P Value of Kendall's W, Cronbach's $\alpha$ <b>NO:</b> IQR of importance (15 items) <b>Group Qualitative Discussion:</b> Need further research	6 sections, 24 items
Round 2: 6 sections, 24 items	<b>Statistical Analysis:</b> <b>Delete:</b> 0 <b>Modify:</b> 6 items <b>Expert's Advice:</b> 6 items received 6 advice and 1 open comments <b>Group Qualitative Discussion:</b> <b>Delete:</b> 0 <b>Modify:</b> 2 items (item 3b, 12b) <b>Add:</b> 0	<b>Statistical Analysis:</b> <b>Yes:</b> IQR of agreement degree, P Value of Kendall's W, Cronbach's $\alpha$ <b>NO:</b> IQR of importance (7 items), F-ratio of agreement degree (9 items) and importance (7 items), absolute difference in CV of agreement degree (13 items) and importance (7 items) <b>Group Qualitative Discussion:</b> Need further research	6 sections, 24 items
Round 3: 6 sections, 24 items	<b>Statistical Analysis:</b> <b>Delete:</b> 0 <b>Modify:</b> 5 items <b>Expert's Advice:</b> 15 items received 19 advice and 1 open comments <b>Group Qualitative Discussion:</b> <b>Delete:</b> 0 <b>Modify:</b> 0 <b>Add:</b> 0	<b>Statistical Analysis:</b> <b>Yes:</b> IQR of agreement degree, P Value of Kendall's W, Cronbach's $\alpha$ <b>NO:</b> IQR of importance (2 items), F-ratio of agreement degree (7 items) and importance (5 items), absolute difference in CV of agreement degree (14 items) and importance (5 items) <b>Group Qualitative Discussion:</b> Terminated	6 sections, 24 items

*Round 2*

In round 2, 6 items met the modify criteria (item 9, 15, 17, 21, 22, 25, all the totally agreement percentage < 70% but > 30%) but no items met the deletion criteria (Table 2, and Table 3). And, 6 items received 6 advice (item 2b, 3b, 6, 13a, 13b, 22 with 1 advice) and 1 open comments. In group discussion, 2 items (Item 3b, 13b) were modified based on the expert's advice. The other items were modified with items description.

As for rounds terminating analysis, the IQR of total agreement percentage, P Value of Kendall's W and the total Cronbach's  $\alpha$  also met the terminate criteria (Table 4). However, the IQR of importance (7 items), F-ratio of agreement degree (9 items) and importance (7 items), absolute difference in CV of agreement degree (13 items) and importance (7 items) did not meet the terminate criteria. Because so many parameters fall in the unsaturated intervals, the research group believed the further research was needed.

*Round 3*

In round 3, 5 items met the modify criteria (item 14, 17, 21, 22, 24, all the totally agreement percentage < 70% but > 30%) but no items met the deletion criteria (Table 2, and Table 3). And, 15 items received 19 advice (item 1a, 10, 12, 18 with 2 advice, item 1b, 2a, 3b, 5, 7, 14, 16, 17, 20, 22, 23 with 1 advice) and 1 open comments. In group discussion, the researchers did not modify the required items because all the advice could be added in the items description.

As for rounds terminating analysis, the IQR of total agreement percentage, *P* Value of Kendall's *W* and the total Cronbach's  $\alpha$  also met the terminate criteria (Table 4). However, the IQR of importance (2 items), *F*-ratio of agreement degree (7 items) and importance (5 items), absolute difference in CV of agreement degree (14 items) and importance (5 items) did not meet the terminate criteria. Although some parameters indicated the information was not saturated, the numbers and differences are much less and smaller than former surveys. More importantly, the research group did not find new information and codes from the expert's advice and comments for the reporting. So, the research group agreed to terminate the survey. All the changed information were detailed in Table 5.

The characters of the IRICA statement

Synthesized all the documents, the authors discussed once more in July 2015 to optimize the descriptions of the checklist, and modified several words and sentences. Basing on the literature reviews, three-waves expert qualitative discussion and three-rounds international Delphi survey, the research group formed the final version of IRICA statement (Improving the Reporting quality of Instrument Cross-cultural Adaptation) which contains 24 items subhead under 6 sections (Table 6, and the Chinese Version in Appendix 10).

**Table 6: The checklists for Improving the Reporting quality of Instrument Cross-cultural Adaptation (the IRICA statement)**



Section/Topic	Item No	Checklist Item
<b>Title and Abstract</b>		
Title and structured summary	1a	Provide the Full name of original instrument, target language, and indicate with words as 'cross cultural adaptation' or 'translation' etc. in the title.
	1b	Structured summary of the translation aims, methods, results, and conclusions.
<b>Introduction</b>		
Rationale and Objective	2a	Describe the objectives and characters of original instrument, and the necessity and benefits for translation research.
	2b	State entire objectives of the research or specific aim of a paper.
<b>Methods</b>		
Authorization	3a	Provide the User- and Translation Agreement from the copyright owner, as well as the authorization date, types and obtaining method.
	3b	Provide the ethics commission name and approval date.
Participants Criteria	4	Provide the inclusion criteria and missions for researchers, experts and examinee in each step.
Forward Translations	5	Provide the research procedure and the number of ForWard Translation versions (FWT-A, FWT-B...).
Forward Synthesis	6	Provide the synthesis procedure, inconsistent identifications and solutions between different FWT versions.
Backward Translations	7	Provide the research procedure and the number of BackWard Translation versions (BWT-a, BWT-b...).
Backward Synthesis	8	Provide the synthesis procedure, inconsistent identifications and solutions among different BWT versions and the original instrument.
Experts Qualitative Review	9	Provide the missions, procedure and terminate criteria of experts qualitative review.
Pilot Testing	10	Provide the methods and procedure for data collection and analysis.
Field Testing	11	Provide the study design, setting, participants, data collection, administration, outcomes, instruments, sample size, etc. The internal consistency, content validity, construct validity and responsiveness must be provided.
Statistical methods	12a	Provide the scoring methods and its meanings.
	12b	Provide all the qualitative and quantitative variables, significant criteria and software.
<b>Results</b>		
Participants	13	Describe the detailed characters of researchers, experts and examinee in each step (a structured form is strongly recommended).
Series Instruments	14	Provide the detailed characters of different versions of translated instrument at each stage (a flow diagram is recommended).
Main results	15	Provide all the results pre-defined in the protocol without publish biases. Otherwise, provide the obtaining methods for more detailed presentation.
Other analyses	16	Provide the exploratory analysis methods and results for unexpected situations.
<b>Discussion</b>		
Summary of evidence	17	Summarize all the positive and negative, qualitative and quantitative, confirmatory and exploratory findings and clues.
Comparison of instruments	18	Longitudinal and parallel compare the differences among original instrument, target translation and other completed translations.
Limitations	19	Describe the advantages and limitations of the study.
Copyright owner interaction	20	Return the research documents to the copyright owner and present the assessments and suggestions, if available.
Application attentions	21	Provide the key information of instrument obtains, administration, analysis and interpretation.
Conclusions	22	Give a total interpretation of the study and inspirations for further research.
<b>Other information</b>		
Appendix	23	Provide the final target instrument, authorizations, ethics permission, series of instruments, etc., if available.
Funding	24	List all the funding and provide their potential influence on the study.

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## Discussion

### *The explanations of IRICA*

#### *Section 1. Title and Abstract*

-item 1a: To concise and clear present the research information, the full name of original instrument, target language, research type and the role of article in series studies should be provided in the title. Of those, the research type can be indicated but not limited to words “cross cultural adaptation”, “cross-cultural”, “cultural adaptation”, “translation” or “translating”, etc.

-item 1b: Although the abstract format in different journals are variously, the translation aims, procedure and corresponding results, statistical methods, and psychological metrics in target language should be provided at least.

#### *Section 2. Introduction*

-item 2a: Briefly describe the basic characters of original instrument, as well as the translation advances in all languages. The rational of translation should be provided clearly, so the evidence based on a comprehensive literature research in the widely used academical platforms in the target language was highly recommended.

-item 2b: Claim the objectives of the whole research and present manuscript.

#### *Section 3. Methods*

-item 3a: Provide the authorization date and types of User-Agreement and Translation Agreement from the copyright owner or author. All the agreements must be obtained before the study beginning and listed in the article appendix. If the copyright is public or free, the authorization was not necessary, but it should be clarified in the article.

-item 3b: Describe whether the study was approved by the ethical commission, and the commission name and approval date if yes.

-item 4: Provide the inclusion criteria and samples for researchers (education degree, specialty, language skills, standard operation procedure trained, etc.), experts (title grade, country/states, research background, etc.), examinee (age, gender, disease, consent, etc.) and their missions in each step. And note that the description of researchers and experts are usually ignored, so much attention should be paid on them.

-item 5-8: They are the core methods sets for CCA research, so the more detailed information the better. The different forward and back translation versions were recommended to being attached to the appendix.

-item 9: Describe the qualitative methods used for forward and back translation, for example, experts item review, focus group, nominal group, cognitive interview, et al. Provide their missions, saturation criteria, and inconsistent solutions.

-item 10-11: Provide the study design, setting, participants, data collection, administration, outcomes, instruments, sample size, etc.. The indicators and criteria for pilot test also should be described. In the psychological properties assessments, the internal consistency, content validity, construct validity and responsiveness must be provided. If applicable, the researcher should provide the test-retest reliability, inter-interviewer reliability, discriminative validity, criterion validity, interpretability, etc.

-item 12: Firstly, provide the scoring methods of the translation instrument and its meanings, for instance, higher or lower scores indicate better or worse health status. And, provide all the qualitative and quantitative variables and significant criteria. In addition, the modern test theory field is extremely quickly, so the item response theory, differential item functioning, equating and linking, response shift, etc. are also highly recommended. The software used in the analysis also should be clarified.

#### *Section 4. Results*

-item 13: The researchers, experts and examinee participated in the complex research with various aims at different stages, their characters are so multiplex that authors usually intentionally or unintentionally ignored the reporting. This may decrease the research quality and result in many confusions on the information resource. Therefore, a structured form was highly recommended to providing their sociological and professional background characteristics (such as gender, age, title, occupation, geographic area, professional background, etc.) at different research stages (such as forward translation, backward translation, experts qualitative review, pilot Testing, field Testing. etc.).

-item 14: Provide the detailed characters of different versions of translated instrument at each stage, including the instrument frame, items number, modifications and related reasons. A flow diagram was recommended in the text or appendix.

-item 15: Provide all the results pre-defined in the statistical protocol without publish biases, regardless positive or negative, good or bad. It is important to note that the psychological properties assessments in field test are the core of instrument CCA research, so the more information the better. The routine analysis contains reliability, validity, responsiveness, interpretation, etc. If the researcher introduced the modern measurement theory, the model assumptions, model fits and item parameters estimation should be described clearly at least. If the publication does not allow for a detailed presentation, reference to a more detailed presentation elsewhere should be made, for example, availability of the full results from the authors or online, or publication of a separate paper.

-item 16: Besides the pre-defined analysis, the exploratory analysis can also be conducted for the subgroups or other temporary situations occurred in the study, but the impact on the primary results needs to be presented. Although some experts claimed that this item is not necessary, the research team believes that CCA research usually faces more unexpected situations than development research, because people lived in different cultures usually have various value systems, goals, expectations, standards and concerns, which maybe result in more unexpected manifestations. So, more attentions on these temporary situations and explanations in the reporting are very necessary for researchers and examinee to understand the uniqueness of the target culture.

#### *Section 5. Discussion*

-item 17: Synthesize all the evidence produced in the study and generate a comprehensive main result, regardless negative or positive, qualitative or quantitative, confirmatory or exploratory findings and related clues. In addition, please interpret and evaluate the relationship between the actual evidences and expecting hypothesis.

-item 18: Firstly, longitudinal compares the different versions of translated instrument generated in the CCA research, especially the original and final targeted instrument, including the instrument frame, scoring and administrative model, psychological properties, etc. The similar parallel comparison of other translated versions should be also provided, especially the distinctive characters of each language.

-item 19: Describe the advantages and limitations of the instrument CCA research, and indicate the impact from the shortcomings and solutions.

-item 20: The authorization from the copyright owner in CCA research is very important. It is equally important that translators should return related documents, results and interpretations of the translation to the copyright owner. If applicable, the assessment and advice from the copyright owner should be also provided. If the copyright is public or free, it is not subject to this restriction.

-item 21: The lack of using strategies usually confusing users once they need the instrument. Please provide the key information of instrument obtaining, paying, printing, administrating, scoring, analyzing and results interpreting.

-item 22: Basing on all the evidences generated in the study, please describe the main findings and give a rational explanation and evaluation, as well as the inspirations of further research.

#### *Section 6. Other information*

-item 23: If the detailed information was not allowed in the text, please provide them as much as possible in the appendix, includes but not limits to the final target instrument, original instrument, research manual, authorizations, ethics permission, series of instruments generated in the CCA procedure, etc.

-item 24: List all the funding and provide their potential influence on present and future studies, including the sponsor's participation degree and impact on the study design, implementation, analysis, and result interpretation.

#### ***Advantages and Limitations***

The main advantage of this study are the comprehensive quantitative analysis with rigorous statistically criteria for the items and rounds analysis for the Delphi survey, which raised the credibility and uniformity. In the meantime, we performed saturated information extraction of expert's qualitative reviews to surmount the possible weaknesses for quantitative analysis.

The primary limitation of this study are that the "final" version of IRICA statement is not really "final" but a preliminary draft, because it lacks of face-to-face consensus discussion, pilot test, international feedback and criticism, etc., accorded to the guidance for developers of health research reporting guidelines[14]. The second limitation are the narrow geographic representation of the experts participated in the Delphi survey, though they have plentiful professional backgrounds and title grades. It may be results in the loss of many cutting-edge views, at least to some extent. Therefore, this statement maybe receives more accusations or oppositions. However, this exact is an important purpose of this paper, which is to seek more and wider professional opinions from global researchers. Any constructive comments, advice and criticisms are welcomed to the corresponding author. The optimization of this statement aims to improve its science and recognition is still continuing.

## **Conclusions**

Based on comprehensive literature reviews and mixed analysis of international experts surveys, this study established a preliminary checklist to improve the reporting quality of instrument Cross-cultural Adaptation research (the IRICA statement), which contains 6 sections and 24 items, and explained its contents in detail. The IRICA statement is developed to help inform the reporting of instrument Cross-cultural Adaptation research. It can also be used in reporting quality evaluation and study design assistant to some extent. It is inevitable that some limitations deduced its recognition, more efforts to enhance its science is going on to improve the overall reporting quality of instruments Cross-cultural Adaptation research.

## **Abbreviations**

Quality of life, QOL

World Health Organization, WHO

Cross-Cultural Adaptation, CCA

CONsolidated Standards of Reporting Trials, CONSORT

STrengthening the Reporting of OBservational studies in Epidemiology, the STROBE

Preferred Reporting Items for Systematic Reviews and Meta-Analyses, PRISMA COnsensus-based Standards for the selection of health Measurement Instruments, COSMIN

Preferred Reporting Items for Patient-Reported Outcome Instrument Development, PROQOLID

Patient-reported outcome, PRO

Guidance on Conducting and REporting DElphi Studies, CREDES

Association for Chinese Quality of Life, WACQOL

Inter-quartile range, IQR

Coefficient of variation, CV

Improving the Reporting quality of Instrument Cross-cultural Adaptation, IRICA

## Declarations

### Ethical Approval and Consent to participate

This study was approved by the Research Ethics Committees in First Affiliated Hospital of Guangzhou University of Chinese Medicine.

### Consent for publication

All authors read and approved the final manuscript.

### Availability of supporting data

The data that support the findings of this study are available on request from the corresponding author, HOU Zheng-kun.

### Competing interests

Non-financial associations that may be relevant or seen as relevant to the submitted manuscript. All authors have completed the ICMJE uniform disclosure form at [www.icmje.org/coi\\_disclosure.pdf](http://www.icmje.org/coi_disclosure.pdf) and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

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### Authors' contributions

Prof. Hou ZK are the guarantor of integrity of the entire study and were responsible for the conception and design of the study, acquisition, analysis and interpretation of data. Prof. LIU FB and Prof. CHEN XL are the advisers for the study. TAN YK, M.D. and CHEN ZQ, M.D. are responsible for the distribution, collection, translation and assembly of the questionnaires and data. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

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