

Translation and Content Validation of the WERF-EPHect Clinical Questionnaire (Standard) into Indonesian: A Standardized Tool for Collecting Clinical Phenotype Data in Endometriosis Patients

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ABSTRACT

Aims and background: Currently, there is no consensus on the standardization of clinical phenotype data for endometriosis patients. The WERF-Endometriosis Phenome and Biobanking Harmonization Project initiated the development of standardization methods for collecting research samples of surgical phenotypes and clinical/biological data related to endometriosis research worldwide. Therefore, translation of the WERF-EPHect Clinical Questionnaire (Standard) (WERF EPQ-S) into Bahasa Indonesia and the validation of this questionnaire is required. To create a standard for taking clinical phenotype data for endometriosis patients by translating and validating WERF EPQ-S content.

Materials and methods: This research was conducted using the transcultural adaptation method. This validation test WERF EPQ-S questionnaire was carried out through a process of forward-backward translation, harmonization by experts, cognitive debriefing to questionnaire targets, and proofreading and finalization by experts.

Results: Translation and validation of the Indonesian version of the WERF EPQ-S questionnaire had 10 stages. There are cultural differences from the country of origin of the questionnaire, including medicines available, medical terms that are common in the country of origin but unfamiliar in Indonesia, and the presentation of racial tribes that do not describe variants of Indonesian ethnic tribes. The duration of finishing the questionnaire population was 79.3 minutes, and out of 116 questions, there were 21 that required to be guided.

Conclusion: The WERF EPQ-S Indonesian version was obtained with contents according to users' needs. Such a transcultural adaptation method is needed for this tool for the population. The WERF EPQ-S version in the Indonesian language is a valid questionnaire and is ready to be applied to endometriosis patients in Indonesia.

Clinical significance: The translation and validation of the WERF-EPHect Clinical Questionnaire into Bahasa Indonesia represent a crucial step toward establishing a standardized and culturally relevant tool for collecting clinical phenotype data from endometriosis patients in Indonesia.

Keywords: Clinical phenotype, Endometriosis, Translation, Validation, WERF-EPHect Clinical Questionnaire (Standard).

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INTRODUCTION

Endometriosis is a chronic inflammatory disease in which there is ectopic endometrial tissue in the pelvic cavity. Endometriosis might affect women's quality of life, with symptoms ranging from menstrual pain, chronic pelvic pain, infertility, and increased risk of malignancy.

Direct visualization of the lesion during surgery, such as a laparoscopy or laparotomy and biopsy, is the gold standard for diagnosing endometriosis. There are several treatment options for endometriosis, such as conservative and surgery. According to ESHRE guidelines, nonsteroidal anti-inflammatory drugs (NSAIDs) and hormone therapies, progestogens, combined hormonal contraceptives, GnRH agonists, or GnRH antagonists are given to treat painful symptoms. However, this treatment can only control the lesion; some cases may require surgery to address. The high recurrence rate after surgery makes some women undergo multiple operations.^{1,2}

Currently, there has yet to be an international consensus on the standardization of clinical phenotype data for endometriosis patients. World Endometriosis Research Foundation is a non-profit

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organization engaged in endometriosis research involving various research centers around the world. One of the major projects is the WERF-Endometriosis Phenome and Biobanking Harmonization Project,³ which initiated the development of consensus standardization methods for collecting research samples of surgical phenotypes and clinical and biological data related to endometriosis research worldwide.⁴⁻⁷

Our study was carried out with the translation and validation of the WERF-EPHect Clinical Questionnaire (Standard) (EPQ-S) into the Indonesian language (Bahasa, Indonesia). This research is expected to be a pioneer in standardizing basic data collection profiles of endometriosis patients in Indonesia leading to high-quality research and breakthroughs for endometriosis patients.

MATERIALS AND METHODS

This research was conducted using the transcultural adaptation method at the Gynecology Clinic, Dr Cipto Mangunkusumo General Hospital. The EPHect EPQ-S questionnaire went through a process of forward-backward translation, a process of harmonization by experts, content validation testing by conducting cognitive debriefing to the target users of the questionnaire, and proofreading and finalization by the experts.

In this study, the workflow is carried out in accordance with the work group of the Quality of Life Special Interest group (QoL-SIG) – Translation and Cultural Adaptation group (TCA group)⁸ with the 10-step methods (Fig. 1). We involved two independent translating centers in the forward translation process (step 2), resulting in two translated questionnaires into Bahasa Indonesia, and some differences between these two were reconciled (step 3). After this process, the questionnaire was backward translated to English (step 4) and reviewed (step 5) to ensure no significantly

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different meanings for every question point between the two languages. All the products of these processes were harmonized (step 6) into one questionnaire by gathering consultants of six senior Gynecology Endocrinologists from the Division of Reproductive Immunoendocrinology, Department of Obstetrics and Gynecology, Dr Cipto Mangunkusumo General Hospital, Faculty of Medicine Universitas Indonesia, as so-called as experts, to produce an instrument for questionnaire targets in the cognitive debriefing process.

The cognitive debriefing process (step 7) is carried out in two stages. In the first stage, individually, the research subjects filled out the questionnaire without being accompanied. The number of respondents is 33. Research subjects are free to fill out or not fill out (if they did not understand). Then, after filling in, in-depth interviews with each research subject and discussion of each number of questions in the questionnaire were performed. The results of in-depth interviews obtained some inputs from each research subject and became material for improving the questionnaire.

After the improvement, the second stage is in focus group discussions consisting of five to eight research subjects filled in individually. From the discussion, each questionnaire number was discussed, focusing on the points that had problems during

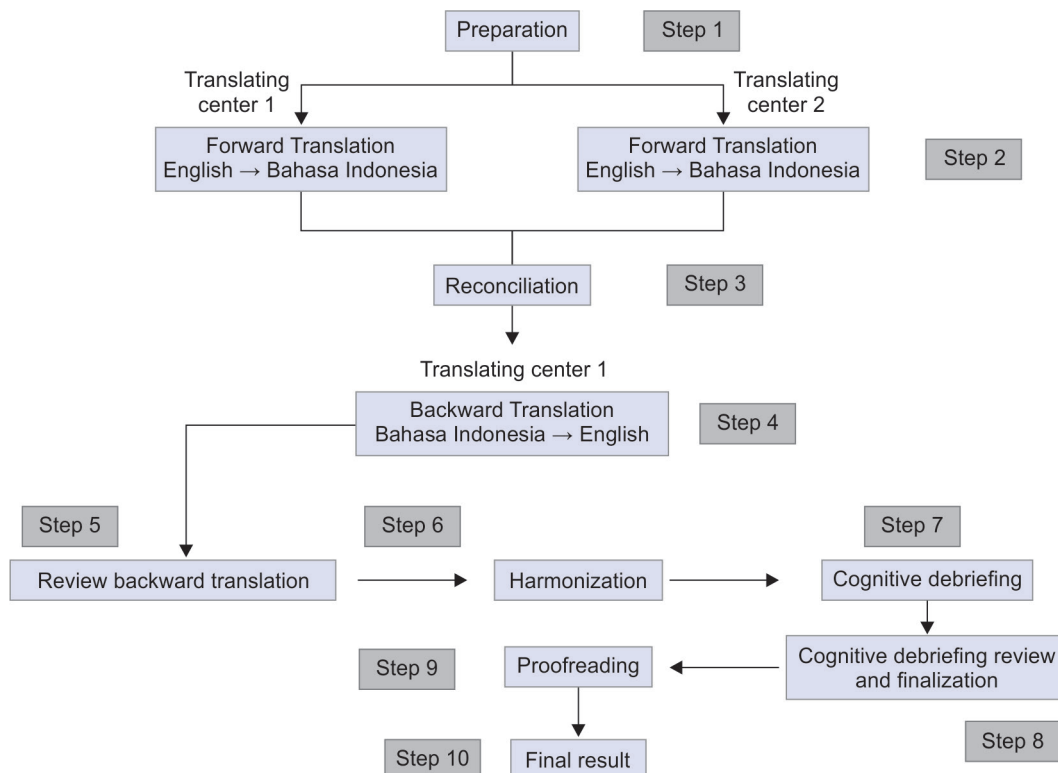


Fig. 1: Workflow of translation and cultural adaptation⁶

Table 1: Characteristics of cognitive debriefing respondents

Variable	(n = 33)
Age	35.7 (33.27–38.13)
Marital status	
Married	26 (78.8%)
Not married	7 (21.2%)
Education	
None	1 (3%)
Elementary	4 (12.1%)
High school	16 (48.5%)
Bachelor degree	11 (33.3%)
Master's degree or above	1 (3%)
Occupation	
Private sector	10 (30.3%)
Governmental sector	3 (9.1%)
Professional	3 (9.1%)
Entrepreneur	1 (3%)
Housewives	16 (48.5%)
Duration of independent filling out the questionnaire (minutes)	79.3 (69.24–89.36)

the previous individual interview. The focus group discussion results then become inputs for further improvement of the questionnaire.

The respondents in this step were all women with a suspicion of endometriosis and with a diagnosis of endometriosis that sought treatment from January 2019 to July 2019.

After cognitive debriefing, the inputs from the questionnaire targets were reviewed and finalized (step 8). Another expert meeting was performed to proofread the final result and validate the content (steps 9 and 10).

RESULTS

Individual cognitive debriefing was performed on 33 respondents; the average age was 35.7. In terms of recent education, there were 16 respondents (48.5%) who were high school graduates. Most respondents' occupations were housewives (48.5%) (Table 1). The duration of filling out this questionnaire independently, without assessing whether or not the respondent understood, was 79.3 minutes.

The cognitive debriefing review and finalization found no significant changes, and almost all items in the questionnaire agreed on grammar and content. The results, included in the front page section, added a list of abbreviations, provided information that several questions will be guided, and explained that progestin pills (e.g., visanne®) are also included in the category of hormonal contraception. The definition of endometriosis was also added so that the patient understands what this definition means, given that this terminology is used frequently in the questionnaires.

About 21 out of 116 questions were decided to be led by the clinician in their filling. Some questions were decided to be guided during the harmonization process, and some during the cognitive debriefing process. The questions decided during harmonization are items seen by experts that the majority of the Indonesian population will need help understanding the purpose of the questionnaire questions. Another thing is that it can contain several medical terms that need explanation. Furthermore, cognitive debriefing inputs from questionnaire targets (the public) added a

few items that were recommended to be guided. It was due to some questions containing medical terms that needed to be explained when read by the respondents themselves.

Some cultural differences from the existing questionnaires with those are including differences in medicines available in Indonesia, and a number of medical terms that may be common in the country of origin of the questionnaire maker but not very common in that country's society, such as ultrasound, TENS, MRI, cesarean section, vaginal and several medical diagnoses (items decided to be guided). Another thing is that including racial tribes displayed in the questionnaire does not reflect the diversity of racial tribes in that country and needs to be adjusted.

DISCUSSION

Content validity refers to the results obtained from a tool, in this case EPHect EPQ, for collecting clinical phenotypic profiles of endometriosis patients and knowing whether the results can adequately describe the profile.⁹ This questionnaire has been used worldwide and adopted in Indonesia to obtain phenotypic data of standardized endometriosis patients. Through the process of translation and validation, this instrument can be used validly in Indonesia by adjusting existing languages and cultures. There are six sections in this questionnaire, and throughout the process, various adjustments were made.

Some of the instruments that have been validated include the WERF-EPHect Clinical Questionnaire (Standard) (EPQ-S), WERF-EPHect Clinical Questionnaire (Minimum) (EPQ-M), WERF EPHect Standard Surgical Form surgery form, WERF EPHect Minimum Surgical, WERF-EPHect SOPs for collection, processing, and storage of fluid biospecimens.³ In the questionnaire, EPQ-S clinical data will be obtained, including pain images, history of subfertility and reproduction, menstrual history, history of hormone use, history of disease and surgery, history of treatment, and personal information, all of which are recommended as standard. As for the more straightforward EPQ-M clinical questionnaire, asking for clinical data is minimally required.^{3,7}

Components assessed and asked for EPQ-S exclude information on psychiatric status and quality of life. Completing this questionnaire from the original study requires 25–40 minutes.⁷ It differs from this study, which required 40 minutes more. This explains that our population needs more time to complete this questionnaire. This questionnaire has been translated into Chinese, Danish, Dutch, French, German, Hindi, Hispanic, Italian, Marathi, Portuguese, Spanish, and Turkish. Arabic, Polish, and Thai are in the process of translation.³ Unfortunately, researchers were unable to find publications related to the process of translating and validating these questionnaires into these various languages. However, data related to filling out questionnaires in various centers of endometriosis are varied. These variations include filled in by respondents themselves while in a health facility, filled online on a computer/tablet, filled in paper and taken home, filled online at home, filled with nurses or research assistants face to face, or filled with nurses or telephone research assistants. Translations in other countries are carried out by centers registered with WERF, and the translation process is shared with the organization.

Further collaboration and harmonization are advised with WERF as an organization engaged in endometriosis research. Other collaboration with research centers around the world is also essential to get involved in WERF – Endometriosis Phenome and Biobanking Harmonization Project, which initiated the development of a

standardization consensus research sample collection methods for surgical as well as clinical and biological phenotype data related to endometriosis research.

CONCLUSION

The translation and validation of the Indonesian version of the WERF EPQ-S has 10 steps. Out of 116 questions of the WERF EPQ-S Indonesian version, 21 questions in the questionnaire had to be guided. Content validation is necessary for a non-Indonesian language questionnaire through transcultural adaptation in order to be used. The WERF EPQ-S version in the Indonesian language is a valid questionnaire and is ready to be applied to endometriosis patients in Indonesia.

Clinical Significance

The translation and validation of the WERF-EPHect Clinical Questionnaire into Bahasa Indonesia significantly impacts endometriosis research by introducing a standardized tool for collecting clinical phenotype data in Indonesia. This adaptation addresses a crucial need for consistency in data collection, ensuring the accuracy and reliability of clinical information. The successful implementation of the Indonesian version not only enhances global collaboration and comparability but also promises to improve patient care through tailored interventions and contribute to advancing evidence-based practices in the challenging realm of endometriosis research.

DECLARATIONS

Ethics Approval and Consent to Participate

This research has undergone scrutiny and received approval from the Ethics Commission of the Faculty of Medicine at the University of Indonesia, under protocol number 18-03-0181. Participants who met the inclusion criteria provided informed consent before engaging in the study.

Authors' Contributions

Data were collected and analyzed by A.M. The manuscript was written by AM and GP. HS, RAW, MM, AKH, KS, and RM designed, conceptualized, and reviewed the manuscript. All authors approved the final version of the manuscript.

Availability of Data and Material

Access to data and materials can be obtained by reaching out to the corresponding author as required.

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