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## Validity and Reliability of the Questionnaire for Assessing Women's Reproductive History in Azar Cohort Study

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### ABSTRACT

This study was done to evaluate the validity and reliability of women's reproductive history questionnaire which will be used in Azar Cohort study; a cohort that is conducted by Tabriz University of Medical Science in Shabestar county for identifying risk factors of non-communicable diseases. Content and face validity were evaluated by ten experts in the field and quantified as content validity index (CVI) and content validity ratio (CVR). To assess the reliability, using test-retest approach, kappa statistic was calculated for categorical variables and intra-class correlation coefficient (ICC) was used for the quantitative items. The calculated CVI and CVR were 0.91 and 0.94, respectively. Reliability for all items was high. The ICC was 0.99 and kappa statistic was equal to 1. The final version of questionnaire was redesigned in 26 items with 7 subscales.

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## Introduction

As a developing country, Iran is experiencing rapid epidemiological transition. The regional cohort studies in Iran such as Tehran Lipid and Glucose Study<sup>1</sup> and Golestan Cohort Study<sup>2</sup> were conducted to identify the incidence and the risk factors of Noncommunicable disease (NCDs).

Following these regional studies, a nationwide cohort study, the prospective epidemiological research studies of the Iranian Adults (PERSIAN), was launched in the 2014 to identify risk factors of NCDs in different regions of Iran.<sup>3</sup> Persian Cohort study includes ten cohorts in ten different regions of Iran. One of these regions is East Azarbaijan province. The cohort in this province, which was nominated as Azar Cohort, is conducted by Tabriz University of Medical Science in Shabestar county.<sup>4</sup> Our study was designed to validate the original questionnaire that had

been designed in Tehran cohort<sup>3</sup> to measure reproductive history of female participants.

## Materials and methods

The original questionnaire of woman's reproductive history included 18 items including 6 subscales. It contains questions about menstruation and menopause, pregnancy, history of breast feeding, history of reproductive system problems, history of drug consumption associated with infertility and contraception, history of breast or cervical cancer screening.

We measured the face and content validity of the questionnaire. Nine gynecologists from Alzahra hospital and three reproductive health professionals from nursing faculty of Tabriz University of Medical Sciences were selected by convenience sampling. For assessing the face validity of questionnaire, we requested

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from experts to write their comments about the location of items, correct scaling and grammatical structure of each item, and the necessity of adding new items or removing existing items. Regarding content validity, we requested from experts to review the questionnaire and assess each item based on 4 criteria including relevancy, clarity, simplicity, and necessity. CVR was calculated based on the responses to the necessity of questions ( $n_E$ ) and the formula of  $CVR = (n_E - N/2) / (N/2)$  was used. To determine the cut-off point for CVR, Law she's table was used.<sup>5</sup> According to Law she, for 10 professionals, minimum required CVR for each item is 0.62. Content Validity Index (CVI) was used based on Waltz and Basel content validity index.<sup>6</sup> CVI for each item was obtained by dividing the number of professionals who ranked the items as compatible or full compatible for each criterion (relevancy, clarity, and simplicity) to the total number of professionals. The average value of three criteria was used as the total CVI for each item. Minimal required amount of CVI for each item was 0.79.<sup>7</sup>

To assess reliability of the questionnaire, 30 females (35-70 years old), participating in the Azar cohort pilot project who met the inclusion criteria (the permanent resident of this city, ability to response to the questions, and Iranian nationality) and exclusion criteria (refusal to participate in the study, having any chronic disease history such as cardiovascular and pulmonary disease) were selected by convenience sampling method. Necessary information obtained in their first visit and other follow ups were done by phone call. To assess the reliability of questionnaire, we used test-retest and intra-class correlation coefficient (ICC) for quantitative variables and Cohen's Kappa coefficient for qualitative variables. An intra-class correlation coefficient or Kappa higher than 0.6 were considered as acceptable.<sup>8</sup> Full description about the questionnaire and the study objectives was given to the participants and informed consent was obtained from them. The study protocol was approved by the ethics committee of

Tabriz University of Medical Sciences (Code Number 5/4/6323).

## Results

The mean age of women was 46.6 years and the mean age at menarche was 13.6 years. About 26.6% of the study population was postmenopausal. The mean age of menopause was 45.5 years for them. On average, each woman gave a birth to 2.73 children, and totally each woman had 21.8 months of breastfeeding. Thirty percent of women have ever had mammography and 93.33% of females had a history of Pap smear test. Among contraceptive methods, 73.33% of women have been used oral contraceptives, and 3.3 % relied on vasectomy. The CVI and CVR were calculated for each item. Minimum and maximum CVR were 0.80 and 1, respectively and for all items, so CVR was higher than acceptance level (0.62). Total CVR for whole questionnaire (average of CVRs of all items) was 0.94. Minimum and maximum CVI (average of CVIs for relevancy, clarity and simplicity criteria) were 0.80 and 0.96, respectively. All items were satisfactory in terms of CVI (higher than 0.79) and no items were removed. Total CVI (average of CVIs of all items) was 0.91. For all items of the questionnaire Kappa statistic and ICC were 1, except for "duration of breastfeeding", "duration of consuming contraceptive drugs", and "frequency of Pap smears", in which the ICC was 0.99.

According to opinion of experts, the item of "menopause following surgery" was added to the subscales of "history of menstruation and menopause". Moreover, three items were added to the subscales of "history of reproductive problems" including "causes of uterus removal", "age at uterus removal", and "causes of ovaries removal". Items of "Infertility causes" and "history of assisted reproductive treatment" were placed in a new subscale of "Infertility and its treatments". Also, subscale of "history of consumption of drug related to infertility and contraception" was converted into two separate subscales of "history of infertility and its treatments" and

“history of contraception”. Moreover, the item of “history of consumption of drugs related to infertility treatment” was replaced in “history of infertility and its treatments” subscale. Additionally, the item of “hormone replacement therapies” was moved to the subscale of “history of menstruation and menopause”. In the subscale of “contraceptive methods”, four items were added including “intrauterine device (IUD)”, “tubal ligation (TL)”, “vasectomy” and “condom”. Besides, according to the comments of professionals, to improve face validity, “hysterectomy” was replaced by “uterus removal”. Finally, questionnaire was restructured in 7 subscales and 26 items.

## Discussion

Our results showed the need for modification of some items in the questionnaire. According to the comments of experts, several important questions were lacking in the initial tool. The items which were added to the questionnaire included the contraceptive methods, reason for ovaries removal and uterus removal. Then, modified questions were organized in suitable subscale. The phrases containing medical terminology were replaced with the more appropriate words. Regarding reliability, as it was expected, there was not much difference between the test and retest. So, the indicators calculated for reliability were high for all items. We couldn't find any study in literature that evaluates the face & content validity of any questionnaire regarding women's reproductive history. Regarding the reliability of women's reproductive history questionnaire, a study in South Korea found that the Kappa for pregnancy history, breastfeeding and reasons of menopause among the postmenopausal women were 0.67, 0.20, and 0.92, respectively.<sup>9</sup> As a whole, the findings of our study propose that the modified version of the questionnaire for women's reproductive history is reliable. However, to maximize the validity, some important items were added, unfamiliar words were replaced by simple ones, and questions were redesigned. So, it is recommended for

researchers of Azar Cohort study to use the modified version of this validated questionnaire in their cohort study.

## Conclusion

According to findings of this study, it seems that the modified questionnaire for reproductive history of woman is a valid and reliable measure. It may be used in Azar cohort study by researchers.

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## Ethical issues

None to be declared.

## Conflict of interest

The authors declare no conflict of interest in this study.

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