CONTENT VALIDITY OF INFERTILITY QUALITY OF LIFE QUESTIONNAIRE AMONG WOMEN WITH INFERTILITY IN TREATMENT

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ABSTRACT

Background: Infertility treatment is highly stressful for women. European Society for human reproduction suggests that measuring the quality of life of infertile women is important for effective psychological care(1).

Objective: The present study aims to establish content validity of Infertility quality of life questionnaire. The researcher aims to measure quality of life using eight major constructs. They are Emotion, Belief, Behaviour, Familial, Marital, Religiosity, Social Self and Treatment. It is a paper pencil test and measures responses of participants on a 5-point rating scale.

Method and Procedure: The study was conducted in two phases. During instrument design phase (phase one), the researcher a) identified the constructs of the questionnaire using in-depth interviews and review of the literature and b) generated items for each construct. Phase two involved face validity, the content validity (expert judgement) and pretesting the questionnaire. The researcher procured feedback from eleven experts to rate each item based on ‘Relevance’, ‘Clarity’ and ‘Necessity’ representing quality of life of infertile women in treatment.

Results: The items with Content Validity Ratio (CVR) of a) 0.75 and above were retained, b) 0.50 and below were eliminated and c) items between 0.75 and 0.50 were modified and retained. The Content Validity Index for Relevance indicates that 75 of the items were ‘Relevant’ and five items required revision. The Content Validity Index for Clarity indicates that 74 of the items were rated ‘Clear’ and six required revision.

Conclusion: In this study, the researcher constructed Infertility Quality of Life questionnaire and using expert feedback enhanced content validity of the questionnaire. The final questionnaire has 80 items. The study concludes that Infertility Quality of Life is a valid instrument which can be used to assess all relevant dimensions of quality of life of infertile women in treatment.

Keywords: Infertility, Quality of Life, Content Validity, Content Validity Ratio, Content Validity Index.

I. INTRODUCTION

Infertility is clinically defined as a disease of the reproductive system defined by the failure to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse (2). Globally, Infertility affects up to 15% of couples who belong to the reproductive age. Infertility is a growing problem in India for the past two decades. Every year, approximately “60-80 million couples in the world are affected by infertility, out of which around 15-20 million (25%) are from India” (3). The current fertility rate for India in 2020 is 2.200 births per woman. There is a 0.9% decline from 2019” (4). “Nearly 27.5 million couples are known to be actively trying to conceive and suffer from infertility in India”. According to The Indian Society of Assisted Reproduction, approximately “10 to 14 percent of the Indian population are suffering from infertility, with higher rates in urban areas” (5). The social set-up of India has strong emphasis on procreation and childbearing. Delay in pregnancy
and infertility is not only an individual’s problem but also a social problem. In all societies, involuntary childlessness is believed to potentially intimidate the stability of individuals, marital relationships, and their social life. Many aspects of infertility and its medical treatments can also be emotionally overwhelming. The medical workup for infertility can be difficult. Post marriage every woman desire childbearing. In spite of technological advancements in assisted reproduction, infertility is an undesired condition. Hence, accepting the diagnosis for infertility can be incredibly painful. The diagnosis of infertility often brings about a range of stressful, emotional reactions, including denial, shock, anger, depression and anxiety (6–8). Also, making decisions about medical treatments for infertility can be stressful (9,10). These decisions may cause the woman and her husband to manage issues of morals and values, societal and family pressures and relationship difficulties. Women forgo their focus on goals of their life such as career, education, personal well-being and other life goals (11,12). It creates insecurity and sadness in the family. Women feel guilty and responsible for the state of childlessness (9,13,14). This affects their psychological well-being. This leads to reduced quality of life. The infertility-related challenges affect their emotions, thoughts and behaviours. Her husband’s support and involvement in dealing with infertility, support from family, parents and in-laws, friends, relatives, colleagues in the workplace and neighbours are other additional challenges.

Quality of Life is an important marker used for research and clinical evaluation of mental health in psychology. Many psychologist and mental health specialists have used quality of life to understand the impact of infertility on couples’ mental health. Infertility has negative effects on quality of life of infertile couples. (15) Understanding Quality of life is important to evaluate treatment outcomes (16) and to enhance the mental and physical health of patients (17). Gigantesco & Giuliani (2011) also highlight the demands for a more appropriate QoL instrument for research and routine evaluation of treatment.

European Society for Human Reproduction and Embryology (2015) suggest identifying and assessing the mental health of women before, during and after Assisted Reproductive Treatment is an essential part of psychosocial care (1). Boivin and colleagues (2011) developed “Fertility Quality of Life” (FertiQoL) questionnaire which comprises of core factors and treatment-related factors. The core factors are “Emotional”, “Relational”, “Mind/Body” and “Social” and “treatment-related” factors are “environment” and “tolerability” (18). Yaghmaei and colleagues (2013) in Iran developed “Quality of Life in Infertile Couple Questionnaire” (QOLICQ). The domains of the questionnaire are “physical”, “psychological”, “spiritual-religious”, “economic”, “affective”, “sexual” and “social” (19).

The literature review suggests that the translated Hindi version of FertiQoL (2011) have been used for clinical and research purposes in India. FertiQoL was translated to 20 languages including Hindi (18). The authors used literature review to generate 302 items in fourteen areas related to infertility. Few of those areas are marriage/partnership, social network, emotions, cognitions, coping, treatment, physical health. They used methods such as expert review, focused group discussion and statistical tests such as item analyses and exploratory factor analysis to arrive at the final questionnaire. The final FertiQoL questionnaire consists of Core module and Treatment module. Core module consists of four subscales (emotional, mind-body, relational and social domains) and Treatment module consists of two subscales (treatment environment and tolerability). FertiQoL is also a generic questionnaire developed with an aim of developing an universal culture fair test. While culture fair questionnaires open possibilities for global generalization of scores, a culture specific questionnaire meets the diagnostic needs of clinicians and researchers pertaining to a population. Hence, there is a need for a culture specific questionnaire. The current study aims to establish the content validity of a questionnaire constructed to measure the quality of life of infertile women in treatment.

II. METHOD

Phase 1 – Instrument design (20,21). This phase involved determining the constructs of the questionnaire, drawing up items and finalising the items that form the Infertility Quality of Life questionnaire.

The study adopted two methods to identify the a priori constructs. They are 1) review of existing literature and 2) in-depth interviews. In-depth interview was the appropriate method because we intended to identify all the aspects related to infertility. The subject domains or constructs identified using in-depth interview are Emotion, Belief, Behaviour, Familial, Marital, Religiosity, Social Self and Treatment.
Initially, the researcher used the inductive method to generate items using the responses from in-depth interviews. Following this, the researcher used reviews of existing scales to edit and add relevant items (deductive method). Rules of thumb followed in item generation are 1) to generate as many items as possible, 2) include items even if they do not fit properly to the defined domain, and 3) to generate items twice to five times as long as the expected no of items in the final scale. The researcher initially generated 135 items in total including all the eight constructs (Emotion, Belief, Behaviour, Familial, Marital, Religiosity, Social Self and Treatment). Then the researcher reduced 135 items to 95 (Appendix B) on the basis of similarity, objectivity, ambiguity and, repetition in concept(22). At this stage, Emotion constructs had 15 items, Belief constructs had 14 items, Behaviour constructs had 17 items, Familial constructs had 8 items, Marital constructs had 12 items, Social Self constructs had 8 items, Religiosity constructs had 9 items and Treatment constructs had 12 items. The researcher wrote items using a five-point Likert scale. Five-point Likert scale is generally suggested and preferred by researcher because a) it is comfortable for the reader to respond, and b) reader has options to choose from instead of completely accepting or completely disagreeing. It is also preferred because a five-rating scale enables a measurement tool to have reliability, validity and degree of differentiation (Krosnick & Fabrigar, 1997). Therefore, the responses are more conducive for multivariate analysis such as exploratory factor analysis, confirmatory factor analysis and structural equation modelling.

Phase 2 – Establishing Face validity, Content validity and pretesting the questionnaire using Cognitive interview.

Face validity, also called logical validity. According to Coaley (2010), “Face validity is best described as ‘acceptability’ and refers to the appearance of assessment material. It is based upon what any respondent thinks is being assessed. One definition might be that a measure is face valid (or acceptable) if it appears to be measuring what it is claimed to measure” (23). Many social scientists say face validity is the first step in validity. It involves any of the following. 1) Obtaining a view from a different person, 2) evaluation by the target population 3) evaluation by end-users or 4) lay-person. In the present study, the researcher conducted face validity from a researcher and an educator (both women).

Content validity is also called astheoretical analysis. It tests content adequacy of each item of the questionnaire by assessing the relevance and clarity. Content validity consists of both qualitative and quantitative components. In content validity, the social and health scientists request subject experts to judge each item of the questionnaire. Qualitative components comprise of the opinion and feedback the subject experts offer relating to the grammatical and contextual meaning of the items while the quantitative components comprise of evaluating each item on its relevance, clarity and necessity of each item on a rating scale. The responses are quantified and formalised using scaling procedures such as the ‘content validity ratio’ calculated for quantifying consensus given by experts, ‘content validity index’ used for measuring proportional agreement, and ‘Cohen's coefficient kappa (k)’ used for measuring inter-rater or expert agreement.

Content Validity Ratio
The experts are requested to specify the necessity of an item for operating a construct. They are requested to score each item from 1 to 3 with a three-degree range of “not necessary, useful but not essential, essential” respectively. Content validity ratio varies between 1 and -1. A higher score indicates further agreement of the experts on the necessity of an item in an instrument. The formula of content validity ratio is CVR= (Ne - N/2)/(N/2), in which the Ne is the number of experts indicating “essential” and N is the total number of experts. The numeric value of content validity ratio is determined using Lawshe Table. For example, if the number of experts is 15 members, and if CVR is greater than 0.49, the item is accepted(24).

Content Validity Index
In reports of instrument development, the most widely reported approach for content validity is the content validity index(25–27).14, 17, 18 The CVI, a proportion agreement procedure, allows two or more raters to independently review and evaluate the relevance of a sample of items to the domain of content represented in an instrument. The experts rate instrument items in terms of ‘clarity’ and ‘relevance’ as per the theoretical definition of the construct on a 4-point ordinal scale ([not relevant], 2[somewhat relevant], 3[quite relevant], 4[highly relevant]).

A researcher then tallies the proportion of cases in which the raters agree and determines the stability of their agreement(25).14 Researchers are instructed to collapse four ordinal response rankings into two dichotomous
categories of responses ("content invalid" and "content valid") and the CVI becomes a two-category nominal scale (25, 28, 29). Davis (1992) recommends a CVI of .80 for new measures (27).

Criteria for Characteristics and Number of Experts

This step entails confirmation by a specific number of experts, indicating that instrument items and the entire instrument have content validity. For this purpose, an expert panel is appointed. The expert panel should be familiar with the content knowledge, represent various fields relevant to the discipline of the study and adequate such that the questionnaire receives valid feedback from as many experts as possible. Determining the number of experts has always been partly arbitrary. Guion (1977), Hambleton & Rogers (1991), Lawshe (1975), Lynn (1986), and Tittle (1982) recommend the use of multiple experts for content validity and quantify judgments using formalized scaling procedures (24, 25, 30–32). It is also advisable to have at least three experts to a maximum of ten experts (25, 33).

Pre-testing questionnaires on the sample prove to be useful in adjusting or modifying tests to suit the need. Cognitive interview is a recently developed method in which feedback from a small sample of the population helps in revising and finalising the items in the questionnaire.

III. RESULTS

Face Validity

The researcher gave the 95-item questionnaire to a researcher and an academician from English language discipline (both women). The researcher requested their opinion after reading the questionnaire in general. The participant offered the following feedback: “The questions are about the delay in pregnancy. Since it covers almost all aspects of a woman’s life when she is struggling to conceive a child the questionnaire is very comprehensive. The questionnaire is a little lengthy and could be emotionally sensitive at times.

The questionnaire was reviewed by a researcher and an academician from English language discipline. The review confirmed that the questionnaire was appropriate for the study purpose. The results from phase one and two show that the questionnaire has adequate face validity, and content validity. This shows that the questionnaire contains relevant statements that could be used to assess the quality of life of infertile women.

Face validity helped the researcher reassure that the items are relevant and generally appropriate. The researcher could proceed with confidence to the next step, i.e. content validity. Feedback from the participant also cautioned the researcher that the questionnaire is emotionally sensitive. The feedback indicates it may be advisable for a psychologist, an infertility specialist, social worker or a sociologist trained in interpersonal or counselling skills to administer the test. In this way, the researcher can ensure ethics and emotional protection of the participant.

Content Validity

The researcher gave the 95-item questionnaire to 11 experts requesting them to review the items and give their opinions. The experts were one Gynaecologist, one nurse, one Psychologist, one Counsellor, two psychotherapists, two Psychiatrists, two academicians from Psychology and one academician from Social Work. The researcher shared the questionnaire containing all the items to the experts either in printed form or through e-mails. The experts were given the instructions mentioned in figure 1.
Respected madam/sir,

The objective of the research is to study the psychological impact of infertility. The items are drawn using in-depth interviews and literature review under eight dimensions and they are 1. Emotion, 2. Belief, 3. Behaviour, 4. Family, 5. Marital, 6. Social Self, 7. Religiosity and 8. Treatment. I request you to validate the given below questionnaire on its relevance, clarity and its necessity and also your qualitative comments as part of the expert review process. The questionnaire is meant for infertile women who are undergoing treatment for infertility.

Please rate them as given below. Also please suggest if any item can be included.

<table>
<thead>
<tr>
<th>Relevance (1 to 4)</th>
<th>Score</th>
<th>Clarity (1 to 4)</th>
<th>Score</th>
<th>Necessity (1 to 3)</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not relevant</td>
<td>1</td>
<td>Not clear</td>
<td>1</td>
<td>Not necessary</td>
<td>1</td>
</tr>
<tr>
<td>Somewhat relevant</td>
<td>2</td>
<td>Item need some revision</td>
<td>2</td>
<td>Useful but not essential</td>
<td>2</td>
</tr>
<tr>
<td>Quite relevant</td>
<td>3</td>
<td>Clear but need minor revision</td>
<td>3</td>
<td>Essential</td>
<td>3</td>
</tr>
<tr>
<td>Highly relevant</td>
<td>4</td>
<td>Very clear</td>
<td>4</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Questionnaire - Instructions

The below given statements with blanks that are related to your emotional experience and what you think or believe of infertility. There is no right or wrong answers. Please read them carefully and enter the score that feels right for you. Please do not think too much to respond. Choose whatever comes to your mind as soon as you read the sentences.

Emotional Aspects

Always – 1, Often – 2, Sometimes – 3, Rarely – 4, Never – 5

<table>
<thead>
<tr>
<th>S.No</th>
<th>Items/Statements</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>Relevance (1 to 4)</th>
<th>Clarity (1 to 4)</th>
<th>Necessity (1 to 3)</th>
<th>Comments/feedback/Modification that you would like to suggest</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>I ___ do not have peace of mind due to infertility</td>
<td>A</td>
<td>O</td>
<td>S</td>
<td>R</td>
<td>N</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Criteria for assessment are

- Construct definitions
  - Emotional dimension includes all the positive and negative feelings and emotions that infertile women experience during their treatment.
  - Cognitive dimension includes the rational and irrational beliefs that women have about infertility.
  - Behavioural dimension aspect includes the actions and responses of women in dealing with infertility treatment.
  - Family dimension includes the problems and difficulties women experience or support in dealing with infertility treatment from her in-laws and other family members.
  - Marital dimension includes both the support and noncooperative behaviour from their husband and women experience during infertility treatment.
  - Social dimension includes the society’s expectations and pressure on the women dealing with infertility treatment.
  - Religiosity dimension includes the beliefs about God that helps or hinders in infertility treatment.
  - Treatment dimension includes the difficulties the infertile women experience during treatment.

Items to be evaluate based on

- Relevance is demonstrated by an item's ability to represent the content domain as described in the theoretical definition.
- Clarity of an item is evaluated on the basis of how clearly an item is worded.
- Necessity resides whether an item is necessary for operating a construct in a set of items or not.

The Experts’ descriptive comments, Content Validity Ratio (CVR) and Content Validity Index (CVI) were used to review and modify the items of the scale. The Probability of chance occurrence and Inter-rater agreement for Relevance, Clarity and Necessity was calculated using SPSS.

Table 1. Items Eliminated or Modified Using Expert Judgements

<table>
<thead>
<tr>
<th>Items</th>
<th>Ne</th>
<th>N</th>
<th>CVR = (Ne - N/2)/(N/2)</th>
<th>Expected CVR</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item 6 -I am ___ angry with myself because I am infertile</td>
<td>6</td>
<td>7</td>
<td>0.71</td>
<td>0.99</td>
<td>Eliminate</td>
</tr>
<tr>
<td>Item 8 -I do not ___ get bowed down when people ask me about pregnancy</td>
<td>6</td>
<td>7</td>
<td>0.71</td>
<td>0.99</td>
<td>Eliminate</td>
</tr>
<tr>
<td>Item 11 -I ___ upset me when other fertile women touch my head and bless me</td>
<td>4</td>
<td>7</td>
<td>0.14</td>
<td>0.99</td>
<td>Eliminate</td>
</tr>
<tr>
<td>Item 12 -I ___ develop an enormous amount of emotional strain during treatment</td>
<td>6</td>
<td>7</td>
<td>0.71</td>
<td>0.99</td>
<td>Modify and Retain</td>
</tr>
<tr>
<td>Item 14 -I ___ worry about my infertility</td>
<td>6</td>
<td>7</td>
<td>0.71</td>
<td>0.99</td>
<td>Eliminate</td>
</tr>
<tr>
<td>Item 16 -I ___ think it is a shame that I am unable to get pregnant</td>
<td>5</td>
<td>8</td>
<td>0.25</td>
<td>0.75</td>
<td>Eliminate</td>
</tr>
<tr>
<td>Item 22 -I ___ my life is incomplete without a child</td>
<td>6</td>
<td>8</td>
<td>0.50</td>
<td>0.75</td>
<td>Eliminate</td>
</tr>
<tr>
<td>Item 27 -I ___ regret that I should have taken care of me as a teenager</td>
<td>5</td>
<td>8</td>
<td>0.25</td>
<td>0.75</td>
<td>Eliminate</td>
</tr>
<tr>
<td>Item 28 -I ___ think external conditions contribute more to my infertility</td>
<td>6</td>
<td>8</td>
<td>0.50</td>
<td>0.75</td>
<td>Eliminate</td>
</tr>
<tr>
<td>Item 29 -I ___ believe that my infertility resulted from my bad childhood</td>
<td>3</td>
<td>6</td>
<td>0.00</td>
<td>0.99</td>
<td>Eliminate</td>
</tr>
<tr>
<td>Item 35 -I talk to people who understand my infertility</td>
<td>6</td>
<td>8</td>
<td>0.50</td>
<td>0.75</td>
<td>Eliminate</td>
</tr>
<tr>
<td>Item 36 -Crying alone helps me relax when I am distressed because of infertility</td>
<td>7</td>
<td>8</td>
<td>0.75</td>
<td>0.75</td>
<td>Modify and Retain</td>
</tr>
<tr>
<td>Item 38 -I lose interest in taking care of my appearance because of infertility</td>
<td>6</td>
<td>8</td>
<td>0.50</td>
<td>0.75</td>
<td>Eliminate</td>
</tr>
<tr>
<td>Item 40 -I play with children to reduce my anxiety caused by infertility</td>
<td>4</td>
<td>8</td>
<td>0.00</td>
<td>0.75</td>
<td>Eliminate</td>
</tr>
<tr>
<td>Item 49 -I am unable to express to others what I experience due to infertility</td>
<td>7</td>
<td>8</td>
<td>0.75</td>
<td>0.75</td>
<td>Modify and Retain</td>
</tr>
<tr>
<td>Item 50 -My spouse supports me during our struggle to overcome infertility</td>
<td>7</td>
<td>8</td>
<td>0.75</td>
<td>0.75</td>
<td>Modify and Retain</td>
</tr>
<tr>
<td>Item 56 -Me and my spouse are happy irrespective of us having a child or not</td>
<td>7</td>
<td>8</td>
<td>0.75</td>
<td>0.75</td>
<td>Modify and Retain</td>
</tr>
</tbody>
</table>
The results of Content validity ratio calculation show that 76 items had CVR equal and above 0.75, which is Good and Excellent. Nineteen items had CVR below 0.75, out of which 15 items were eliminated. The eliminated items are ‘Item 6, Item 8, Item 11, Item 14, Item 16, Item 22, Item 27, Item 28, Item 29, Item 35, Item 38, Item 40, Item 57, Item 72, and Item 81. For example, Item 27 “I regret that I should have taken care of me as a teenager”, Item 8 “I do not get bowed down when people ask me about”, and Item 81 “I will be sent to hell if I don’t get pregnant”. Reasons for low ratings by the experts were that the items were similar, repetitive, too specific and not representative of the construct.

Item 10, Item 12, Item 20 and Item 95 were below the minimum CVR value. Based on the Lawshe table they had to be eliminated, but the researcher decided to retain the items because of their importance in defining the scale. The items were modified using CVI for Relevance and Clarity and expert comments. After the researcher’s decision about retaining or eliminating of the items, Content Validity Index for Relevance and Clarity was calculated for each item. The items were modified based on ‘Relevance’ and ‘Clarity’ and expert comments on every item.

One suggestion given from most of the experts for the questionnaire was to change items from statements with ‘blanks’ to ‘complete’ statements such that all of them follow a similar pattern such as choosing options. For example, the item ‘I ___ deny that I am infertile’ has a blank and the response choices range from ‘always’ to ‘never’. The blank was removed and the statement was modified as ‘I deny that I am infertile’ with response choices ranging from ‘strongly agree’ to ‘strongly disagree’. It was also suggested to change the rating scale from ‘occurrence’ to ‘agreeableness’. Hence, the rating was changed from ‘Always, Often, Sometimes, rarely and Never’ to ‘Strongly Agree, Agree, Neither Agree nor Disagree, Disagree and Strongly Disagree’ and the sentences were modified accordingly.

The Content Validity Index for Relevance(25) was 0.86 and above for most of the items which are interpreted as ‘Appropriate’. Items 44, 45, 47, 48, 49 had CVI below 0.71 which is interpreted as ‘Need for Revision’.

Similarly, the Content Validity Index for Clarity(25)was 0.86 and above for most of the items which are interpreted as ‘Clear’. Items 13, 21,25, 46, 50, 53 had CVI below 0.71, which is interpreted as ‘Need for Revision’.

After elimination of few items based on expert judgement, emotion domain has 8 items, belief domain has 10 items, behaviour has 13 items, familial has 9 items, marital domain has 13 items, religiosity has 8 items, social self has 7 items and treatment has 13 items. The Infertility Quality of Life questionnaire has 80 items in total.

The inter-rater reliability was calculated using Fleiss Kappa, which is an extension of Cohen’s Kappa used to measure agreement between three or more raters. The calculated Kappa value was 1 for ‘Relevance’, ‘Clarity’ and ‘Necessity’ which is interpreted as ‘Almost Perfect agreement’. The finding indicates that the inter-rater agreement between the expert’s judgments is high and reliable(34).

**Pre-testing the Questionnaire**

After content experts, the actual participants are the best judges to help researchers decide the representative property of the test. Cognitive interview is one such method where a sample of the population preferably between 2 and 5 are requested to verbalize their understanding of each item or statement in the questionnaire. Their response helps the researcher to make necessary changes to the questionnaire. The questionnaire is administered...
to a sample outside the study sample or on a sub-set of the study sample. However, this is an important step before finalising the test.

In the present study, as the last step of phase two, the questionnaire was administered to five infertile women in treatment. Since, infertility QoL questionnaire is sensitive and emotionally overwhelming, the participants were asked to review the questionnaire in privacy. The participants gave a written feedback for the overall questionnaire. For example, “All questions are perfect to know what is going on inside anyone who is going through the infertility treatment”. The feedback was reassuring that the questionnaire covered all aspects related to infertility.

IV. DISCUSSION

Using opinions of patients and reviewing relevant literature, the present study has found that there are eight major constructs that constitute Infertility Quality of Life. They are Emotion, Belief, Behaviour, Family, Marital, Religiosity, Social Self and Treatment. These factors are in line with the findings of studies conducted by the WHO (1996), Rashidi (2008), Boivin (2011), Yaghmaei (2013) and Bakthiyar (2019).

Bakhtiyar (2019) in her study confirmed that infertility can possibly affect many aspects of women’s quality of life such as physical health domain, mental health domain, social domain and the total quality of life significantly (Bakhtiyar et al., 2019). World Health Organization (1996) conceptualizes QoL as consisting of “physical”, “psychological”, “social” and “environmental” - and a “general factor”. Rashidi and colleagues (2008) measured Health-related quality of life using the “Short Form Health Survey-SF-36” (Rashidi et al., 2008). It has eight subscales/domains. They are “physical functioning (PF)”, “role physical (RP)”, “bodily pain (BP)”, “general health (GH)”, “vitality (VT)”, “social functioning (SF)”, “role emotional (RE)” and “mental health (MH)”.

“Fertility Quality of Life” questionnaire (Boivin et al., 2011) which comprises of four core factors and two treatment-related factors. The core factors are “Emotional”, “Relational”, “Mind/Body” and “Social” and “treatment-related” factors are “environment” and “tolerability”. Yaghmaei and colleagues (2013) in Iran developed “Quality of Life in Infertile Couple Questionnaire” (QOLICQ) (Yaghmaei et al., 2013). The domains of the questionnaire are “physical”, “psychological”, “spiritual-religious”, “economic”, “affective”, “sexual” and “social” (Yaghmaei et al., 2013).

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The Infertility Quality of Life questionnaire is culturally sensitive to India and in this way uniquely differs from the above-mentioned questionnaires. The Quality of Life in Infertile Couple Questionnaire also has a ‘spiritual-religious’ dimensions sensitive to Iran. The present study has identified that religiosity as one of the significant component of Infertility Quality of Life.

The FertiQoL (18) and the Fertility Problem Inventory (FPI)(1999) (35) are potentially useful measures of infertility-related QoL (36). Boivin and colleagues (2011) has used literature review and expert consultation to generate potential item, classify items to major constructs and reduce item pool or eliminate redundant items. They have not mentioned the methodology or procedure they used to eliminate items from the initial pool using expert consultation.

Fertility Problem Inventory (35) used Differential Reliability Index to ensure that content saturation of items was relatively high compared with social desirability. Any items that elicited marked tendencies to respond in a socially desirable manner were eliminated. But, a validation study of the Fertility Problem Inventory in Iranian infertile patients established content validity by calculating content validity indices for relevance, clarity and comprehensiveness of the tool.

The sample of the study are infertile women undergoing treatment. The researcher approached the participants in an infertility clinic. The participants were not very comfortable in discussing each item in detail. This could be because of various factors such as emotional sensitivity of the items, preoccupation about their treatment procedure and other responsibilities. In future, researcher can attempt to meet the participant in a relaxed setting other that hospital environment.

After elimination of few items based on expert judgement, emotion domain has 8 items, belief domain has 10 items, behaviour has 13 items, familial has 9 items, marital domain has 13 items, religiosity has 8 items, social self-perception has 7 items and treatment has 13 items. The Infertility Quality of Life questionnaire has 80 items in total.

Based on the findings the Infertility Quality of Life questionnaire can be considered a valid questionnaire for assessing quality of life of infertile women. Yet, the questionnaire is required to undergo rigorous process of further testing for reliability and validity to enhance generalizability of data collected such as internal consistency, construct validity, test-retest reliability, composite reliability, convergent and discriminant validity. These tests require more samples of data from the target population i.e. infertile women undergoing treatment. Content validity is basically a proof or approval from content experts, lay people and target population that the researcher will assess what he/she is intending to assess.

V. FUTURE DIRECTIONS AND CONCLUSIONS

Infertility Quality of Life is a multi-dimensional questionnaire consisting of 80 items in total. The questionnaire uses 5-point rating scale to record the responses. The questionnaire measures quality of life of infertile women in the following major constructs. They are Emotion, Belief, Behaviour, Familial, Marital, Social self, Religiosity and Treatment. The Content Validity Ratio and Content Validity Index are ‘moderate’ and ‘high’. The study concludes that Infertility Quality of Life is a valid instrument which can be used to assess all relevant dimensions of quality of life of infertile women in treatment. Though, the questionnaire is valid, it requires further analysis such as construct validity and reliability to improve the dependability and generalizability of the data collected using Infertility Quality of Life questionnaire.

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