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Designing and Validating Infertility Data Recording Tools in Iran

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Abstract

Objectives: Considering that the prevalence of infertility in Iran is higher than the world average and there is no system for recording these individuals' data, this study aimed at designing and validating infertility data recording tools in Iran.

Materials and Methods: This questionnaire study was conducted in Tabriz in 2019. Five areas were prepared for the questionnaire (i.e., in vitro fertilization or intracytoplasmic sperm injection, intrauterine insemination, ovulation induction) and treatment outcomes) and used after reviewing the studies. The Delphi quantitative technique was applied to standardize and validate the questionnaire through evaluating five infertility specialists. The content validity index (CVI), content validity ratio (CVR), and coefficient of agreement (Cohen's kappa coefficient) were employed to assess content validity through a quantitative approach. Finally, the reliability of the questionnaire was evaluated using the Kuder-Richardson formula through the evaluation of 50 infertile couples visiting AL-Zahra specialized and super-specialized hospital in Tabriz.

Results: The CVI and CVR of all items were calculated and obtained greater than 0.8 except for items 8, 17, and 18 and thus were identified as appropriate items in the questionnaire. Kappa coefficients (k) were also calculated and found to be greater than 0.8 for all items except for the three above-mentioned items. The items with lower than an acceptable CVI, CVR, and k were modified, and the k of the total items was obtained as 0.95. Eventually, the reliability of the questionnaire and its domains were assessed, and the reliability coefficient of the questionnaire was higher than 0.64, which was acceptable.

Conclusions: A questionnaire was designed to evaluate the history and clinical problems of infertile couples with 5 domains and 61 items to record their information (desirable validity and reliability) in their clinical records.

Keywords: Infertility, Registry system, Questionnaire, Validity and reliability, Infertile couples, Tabriz, Iran

Introduction

Infertility is an important factor in reproductive health and a global health issue. More precisely, it is recognized as a crisis that has the potential to threaten the stability of individuals, family relationships, and societies in all cultures (1). According to the World Health Organization (WHO), it is defined as the failure to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse (2).

The infertility burden is 1.9%-10.5% of child-seeking women worldwide, and it was estimated that nearly 48.5 million couples to be infertile in 2010 (3). Its prevalence was estimated as 10% in couples worldwide (4). Infertility is neglected in developing countries. According to WHO, one in every four couples was found to be affected by infertility in these countries (4). The prevalence of lifetime primary infertility was estimated to be 2.8% in 2001 and 21.9-24.9% in 2010 in Iran (5,6). However, the pooled prevalence of primary and secondary infertility was reported to be 5.2% and 3.2%, respectively (6). Infertile couples struggle with problems such as high treatment costs, depression, anxiety, stress, hopelessness, sexual dysfunction, social stigma, and decreases in self-esteem decline. It is considered as a factor for divorce in Iran because of the specific cultural and social context (7).

Nonetheless, little attention is paid to the registry of infertility data and infertility registry system based on international standards despite positive advances in the systematic registry of many diseases in Iran (8). As a result, the unavailable fully qualified infertility dataset in Iran poses a challenge for infertility management and prevention (9).

In this respect, designing and using suitable tools in the infertility information registry system help the users (especially obstetrics, gynecologists, urologists, embryologists, infectious disease specialists, and general

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Key Messages

- Recording infertile women can be effective in planning
- History of infertility and diseases, paraclinical reports, treatment plans and treatment results were designed as a questionnaire for infertile couples
- Infertility registry tool in Iran has acceptable validity and reliability for registering couple information.

practitioners) to use, compare, analyze, and study infertile couples with rapid and simple access to infertility data. The system also helps in planning, implementing, and evaluating the infertility-related activities of public health centers and clinics (10). In their review study on the system of infertility registration in European countries, Safdari et al (1) criticized the lack of an infertility information system in Iran and highlighted the necessity of designing such a system and thus suggested that researchers design such a system. It should also be noted that several systems attempted a similar system in Iran, including Assisted Reproductive Technology (11), the National Assisted Reproductive Technology Surveillance System (12), the Human Fertilization and Embryology Authority (13), and United States Information System (14) which were based on the recommendations of the WHO (15). This system should address the shortcomings of similar systems in Iran to make it more efficient. Therefore, the present study aimed to design a specific registry tool for collecting infertility information on infertile couples and assessing the validity and reliability of the tool in the comprehensive registry system in Iran.

Materials and Methods

This descriptive and methodological study evaluated the validity and reliability of the infertility registry tool specialized to infertile couples. It is worth mentioning that it was attempted to use the basics of the questionnaire construction (instrumentation in Iran) similar to other similar studies (16,17). In this regard, all the information in the clinical records of infertile couples referring to infertility clinics under the supervision of an infertility physician was extracted, reviewed, and then meta-analysis studies were performed, and finally, the opinions of specialists were used in terms of infertility and methodology.

Questionnaire Design

A questionnaire with 5 domains, including demographic data, medical history, para-clinical reports, and treatment plans (i.e., in vitro fertilization [IVF] or intracytoplasmic sperm injection, intrauterine insemination, ovulation induction), and treatment outcomes was designed through reviewing the literature and expert opinions. In other words, by gathering data from infertile couples' medical records, basic information was obtained and then the applied data in similar systems (e.g., 14,18) were collected based on review studies and placed in the hands of instrumentation experts to identify the case use design.

(1) Demographic data consisted of 10 questions including name and sure name, national number, date of birth, place of birth, date of visit(s), presenting hospital name, home and mobile phone number, education, occupation, and E-mail-address.

(2) Medical history covered 35 questions on anthropometric parameters (e.g., weight, height, and body mass index), blood pressure, puberty age, type of infertility, type of marriage, previous marriage, and a history of infertility and diseases, particularly immunological disease. The other areas of focus were a history of sensitivity to a particular drug or food, drug history, history of hospitalization, surgery history, and a history of chemotherapy or radiotherapy in the head, neck, or pelvis, alcohol abuse, smoking cigar, and use of hubble-bubble or addictive substances. Required data further included a history of exposure to toxic chemicals, toxic environment, or extreme temperature, history of trauma or injury to male genitals, frequency and duration of intercourse, duration of menstrual bleeding, intervals between periods, and frequency of previous pregnancies. Moreover, other questions were related to a history of recurrent miscarriage and gestational age of the fetus at the time of abortion, frequency of ectopic pregnancies, history of stillbirth, frequency of preterm births in previous pregnancies, history of cervical biopsy, and history of infertility treatment methods. The remaining items belonged to the number of retrieved oocytes, number and quality of embryos in previous IVFs, number and quality of previously transferred embryos, day 3 or 5 embryo transfer, history of preimplantation genetic screening (PGS) in previous embryos, history of ICSI in infertility treatment and assisted hatched embryo transfer, and history of curettage.

(3) Para-clinical data included laboratory tests and ultrasound assessments for women and laboratory tests only for men.

(4) Treatment plans consisted of 8 questions on pregnancy via embryo donation, pregnancy via oocyte donation, consumption of medications and their dosage for the stimulation of the ovarian cycle, and numbers and mean size of follicles in vaginal ultrasound. Other items were related to the type of the IVF treatment protocol, the interval between the current protocol and previous oocyte retrieval, number of retrieved oocytes during the current oocyte retrieval, and number of transferred embryos.

(5) Treatment outcomes encompassed 12 questions on the date of a positive pregnancy test, the number of retrieved oocytes, number and quality of the embryo in the current IVF, number and grade of the currently transferred embryos, blastocyst transferred embryos, and history of PGS in current embryos. Other questions addressed the results of ultrasound and the first and second screening tests, history of cervical insufficiency, and the

need for amniocentesis and McDonald cerclage procedure in the current pregnancy. Eventually, other obtained data included a history of diseases (e.g., hypertension, thyroiditis, and their treatment in the current pregnancy), history of hospitalization in the current pregnancy, and termination of pregnancy due to underlying pathological causes.

Validity and Reliability

Validity refers to accurately measuring what it claims to measure while reliability is the assessment of the reproducibility and consistency of a measurement tool or an instrument (19,20).

Validity Assessment of the Designed Questionnaire

There are different dimensions of validity. We applied two types of validity in this study: Face validity and content validity.

(a) Face Validity

Face validity and content validity were assessed to validate the questionnaires. Six infertility specialists and epidemiologists assessed the face validity of the questionnaires by evaluating difficulty, inconsistency, the ambiguity of questions, and misinterpretation of the items, which were later modified according to their comments. Nevertheless, slight changes were made to the items.

(b) Content Validity

The experts were asked to give their written comments about the structure of questions, including grammar, choice of words, importance, and order of items in the qualitative approach.

The items were modified according to their comments. Then, the content validity ratio (CVR) and content validity index (CVI) were calculated to assess content validity in the quantitative approach. The questionnaire was mailed to five obstetricians and infertility specialists who were asked to fill out the questionnaire using 'necessary', 'necessary but not useful', and 'not necessary' terms. The CVR was computed using the following formula:

$$CVR = \frac{n - \frac{N}{2}}{\frac{N}{2}}$$

where n represents the number of experts who used the "necessary" term and N denotes the total number of the experts. The calculated CVR was compared with Lawshe's table (21), and CVR > 0.8 was acceptable.

To compute CVI, the questionnaire was re-mailed to the five above-mentioned experts who were requested to give their opinions about relevance and transparency using a five-point Likert-type scale (ranging from 1 to 4 representing 'not relevant', 'relatively relevant', 'relevant', and 'thoroughly relevant'). The CVI was calculated using the formula:

$$CVI = \frac{\text{number of raters giving rating of 3 or 4}}{\text{Total number of raters}}$$

where n indicates the number of experts giving the highest scores (scores 3 and 4) to each item and N is the total number of experts (21,22), and CVI>0.8 was acceptable.

The coefficient of agreement (Cohen's kappa coefficient) was used to assess content validity. Kappa coefficient (Cohen's kappa coefficient) evaluates the consistency and correlation of scores given to an item by the observers, reviewers, or appraisers. It ranges from zero to one and is expressed in percentage (23,24). Excel was used to perform the calculations.

Reliability Assessment of the Questionnaire

The Kuder-Richardson Formula (KR) was used to measure the reliability of the questionnaire. It assesses the ratio of yes-to-no answers given to each item and is useful when items consist of yes/no options receiving a score of 1 or 0, respectively (25-27). KR >0.64 is acceptable. Two formulas are available for the KR calculation. The second formula was used in the present study.

Formula I:

$$r_1 = \frac{n}{n-1}\left(1 - \frac{\sum pq}{s^2}\right)$$

where n, p, q, and s^2 represent the number of items, the ratio of correct answers, the ratio of wrong answers, and the variance of the total scores, respectively.

Formula II:

It is used for items with the same difficulty.

$$r_2 = \frac{n}{n-1}\left(1 - \frac{\bar{x}(n-\bar{x})}{nS^2}\right)$$

where n, s^2, and x denote the number of items, the variance of total scores, and mean of scores, respectively. For this purpose, the validated version of the questionnaire was completed by 50 infertile couples visiting Al-Zahra specialized and super-specialized hospital in Tabriz.

Results

The mean (standard deviation) age of men and women was 37 (6.1) and 32.5 (6.8), respectively, and 30% of men and 70% of women were self-employed and housewives, respectively. Less than half of women (46%) and men (36%) had an academic degree. More than two-thirds of the couples suffered from primary infertility.

The CVI of all items was greater than 0.8 except for items 8 (history of immunological disease) and 17 (previous exposure to temperature). The items with CVI> 0.8 were

suitable while those with CVI<0.8 were unsuitable and deleted (CVI<0.6 in items 8 and 17) accordingly (Table 1).

Based on the results, the CVR of all items was equal to or greater than 0.6 except for items 8 and 17. The items with 0.6<CVR<0.8 were modified (items 2, 11, 14, 18, 19, 20, 33, 35, and 59), and the CVR of the remaining items was greater than 0.8, indicating necessary and important items (Table 1). Question 8 (history of immunological disease) was merged with question 7 (history of diseases particularly immunological disease). Similarly, question 17 (previous exposure to temperature) was merged with question 15 (previous exposure to toxic chemicals and

Table 1. The CVR and CVI Values and Coefficient of Agreement (Kappa) on the Infertility Information Registry Tool Specific to Infertile Couples With Respect to the Domains of the Questionnaire

	Couples' Medical History	CVI	CVR	Kappa
1	Weight, height, BMI, and BP	1	1	1
2	Puberty age	0.8	0.6	0.8
3	Type of infertility (primary/secondary)	1	1	1
4	Type of marriage (Permanent, non-permanent, and multiple marriages)	1	1	1
5	Previous marriage in a man and woman (yes/no)	1	1	1
6	History of infertility in a previous marriage of a man or woman	0.8	1	0.8
7	History of diseases, particularly immunological disease (yes/no, name of the disease)	0.8	1	0.8
9	History of drug or food allergies, and the like (yes/no)	1	1	1
10	Specific drug use (yes/no, name of the drug or drugs)	1	1	1
11	Previous hospitalization (yes/no, reason for hospitalization)	0.8	0.6	0.8
12	History of previous surgery (yes/no, name of the surgery)	0.8	1	0.8
13	Already got chemotherapy (yes/no)	1	1	1
14	History of radiotherapy in the head, neck, or pelvis (yes/no)	0.8	0.6	0.8
15	History of cigarette smoking, alcohol drinking, substance abuse, and Hookah use	1	1	1
16	Previous exposure to toxic chemicals and toxic environmental or extreme temperature (yes/no)	1	1	1
18	Disease history (i.e., diabetes, amenorrhea, hypertension, surgery of ovarian, ovarian torsion, ovarian cancer, oophoritis, PID, hirsutism, history of genetic abnormalities) in a woman (yes/no)	0.8	0.6	0.8
19	History of trauma or injury to male genitals	0.8	0.6	0.8
20	Disease history (e.g., Anorchia, history of genetic abnormalities, cryptorchidism, orchitis, varicocele, testis torsion, and sperm analysis problems) in man (yes/no)	0.8	0.6	0.8
21	Frequency and duration of intercourse	1	1	1
22	Duration of menstrual bleeding, intervals between periods, and frequency of previous pregnancies	1	1	1
23	History of recurrent miscarriage and gestational age of the fetus at the time of abortion and frequency of ectopic pregnancies	1	1	1
24	History of stillbirth and frequency of preterm births in previous pregnancies and history of curettage	1	1	1
25	History of cervical biopsy	1	1	1
26	History of infertility treatment methods (e.g., IVF, IUI, oocyst donation, sperm donation, and embryo donation; yes/no)	1	1	1
27	Number of retrieved oocytes	1	1	1
28	Number and quality of embryos in previous IVFs	1	1	1
29	Number and quality of previous transferred embryos	1	1	1
30	Day 3 or day 5 of embryo transfer (yes/no)	1	1	1
31	History of PGS in previous embryos (yes/no)	1	1	1
32	History of ICSI in infertility treatment (yes/no)	1	1	1
33	Use of the fetal hatching technique in the pre-transfer stage (yes/no)	0.8	0.6	0.8
Para-clinical data of couples				
34	FBS, CBC, and hormonal tests	0.8	0.6	0.8
35	Peroxidase test and prolactin	1	1	1
36	Ovarian reserve test results (e.g., AMH, FSH levels on the third day after menstruation, and estradiol)	1	1	1
37	Ultrasound results (Uterine 2 horns, ovarian and uterine vessels, TVS, and HSG test)	1	1	1
Para-clinical data of couples				
38	Antral follicle count	1	1	1
39	Results of sperm analysis, DFI, and Diff quick test	1	1	1
Treatment plans for couples				
40	Pregnancy via embryo donation	1	1	1
41	Pregnancy via oocyte donation	1	1	1

Table 1. Continued

Couples' Medical History		CVI	CVR	Kappa
42	Medications and their dosage for the stimulation of the ovarian cycle	1	1	1
43	Numbers and mean size of follicles in vaginal ultrasound	1	1	1
44	Type of the IVF treatment protocol (e.g., Long agonist, micro flare, and antagonist)	1	1	1
45	Name of the author of the gynecologist IVF protocol, Name of gynecologist performing AVF Fetal transplant gynecologist specialist	1	1	1
46	Interval between the current protocol and previous oocyte retrieval, Number of retrieved oocytes during the current oocyte retrieval, number of the transferred embryos	1	1	1
Treatment outcomes for couples				
47	Date of the positive pregnancy test	1	1	1
48	Number of the retrieved oocytes and the number and the quality of the embryo in the current IVF	1	1	1
49	Number and grade of the current transferred embryos	1	1	1
50	Blastocyst transferred embryos	1	1	1
51	History of PGS in current embryos (yes/no)	1	1	1
52	Results of ultrasound and the first screening tests	1	1	1
53	History of cervical insufficiency (yes/no)	1	1	1
54	Need for the amniocentesis procedure in the current pregnancy (yes/no, results)	1	1	1
55	Need for the Macdonald cerclage procedure in the current pregnancy	1	1	1
56	History of diseases such as hypertension, thyroiditis, and their treatment in current pregnancy	1	1	1
57	Results of ultrasound and the first and the second screening tests	1	1	1
58	Results of GTT and TSH tests in the current pregnancy	1	1	1
59	History of hospitalization in current pregnancy	0.8	0.6	0.8
60	Termination of pregnancy due to underlying pathological causes	1	1	1
61	Premature rupture in the current pregnancy	1	1	1

Note. BMI: Body mass index; BP: Blood pressure; CVI: Content validity index; CVR: Content validity ratio; GTT: Glucose tolerance test; TSH: Thyroid-stimulating hormone; PID: Pelvic inflammatory disease; IVF: In vitro fertilization; IUI: Intrauterine insemination; PGS: Preimplantation genetic screening; ICSI: Intracytoplasmic sperm injection; FBS: Full blood count; CBC: Compelte blood count; AMH: Anti-Mullerian hormone; FSH: Follicle-stimulating hormone; TVS: Transvaginal sonography; HSG: Hysterosalpingography; DFI: DNA Fragmentation Index; AVF: Arteriovenous fistula;

toxic environmental or extreme temperature).

The Kappa of items 8 and 17 was less than 0.4, thus they were excluded from the questionnaire. The Kappa of the remaining items was greater than 0.8 (Table 1), and that of the total items was 0.95 (Table 2).

The reliability coefficient of the whole questionnaire was higher than 0.64, which was acceptable. Further, the reliability coefficient of the domains was higher than 0.64 except for para-clinical data and treatment outcomes (Table 2).

Figure 1 illustrates the strong positive relationship between the total score and medical history domain (r=0.92, $P=0.001$). Moreover, there is a moderate relationship between the total score and par-clinical data domains due to outliers (r=0.5, $P=0.001$), as well as a weal relationship between the total score and treatment plans (r=0.4, $P=0.004$). However, no correlation exists between the total score and treatment outcomes (r=0.4, $P=0.12$).

Discussion

To the best of our knowledge, this is the first study that has designed a reliable and valid tool for registering the data of infertile couples in the infertility registry system in Iran. The tool can be used at individual (treatment plans and outcomes), organizational (quality control and performance evaluation), national, and international

Table 2. Reliability and Validity Coefficients of the Infertility Information Registry Tool Specific to Infertile Couples With Respect to the Domains of the Questionnaire and the Whole Questionnaire

Items	Reliability Coefficient	Coefficient of Agreement
Total score	0.79	0.95
Medical history	0.77	0.93
Par-clinical data (laboratory and ultrasound results)	0.3	0.92
Treatment plans	0.71	1
Treatment outcomes	0.4	0.98

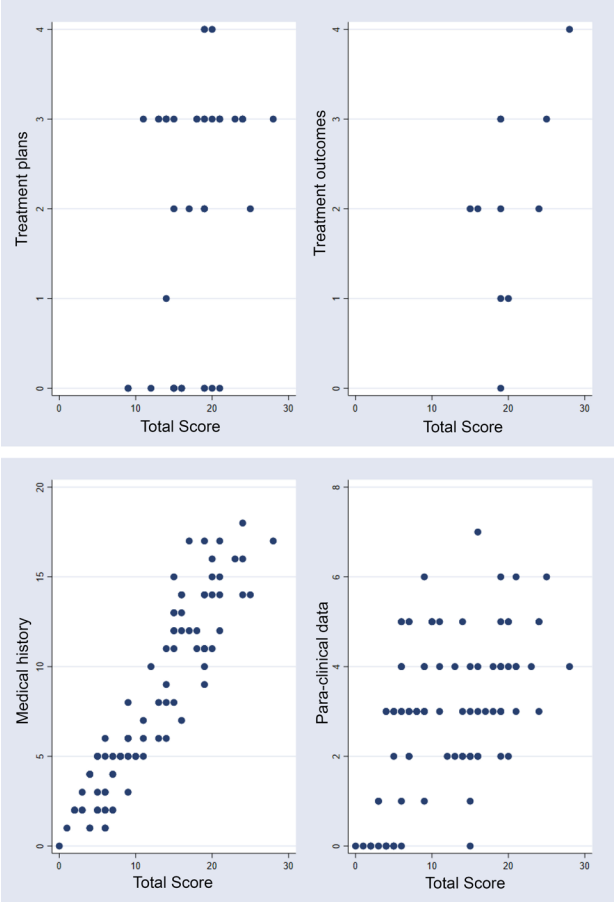

Figure 1. Correlation Between the Total Score and Domains of the Infertility Information Registry Tool Specific to Infertile Couples

(the comparison of results at a broad extent) levels (28). The researchers of the present study believe that the clinical information and records of infertile couples have highly important information that may be forgotten in their frequent referrals to the physician because they are extremely extensive. Patients may also be affected, thus gathering this information and including it into a questionnaire for further use and extraction of accurate information can be highly effective for the physician and improve the results.

Delphi results showed that most experts agreed on the tool and considered it suitable for data registration. The use of the Delphi method allows experts to truly reflect the reality without knowing each other, affecting the final validity and having positive effects, thus making the questionnaire stronger. This instrument consists of 5 domains of demographic data, medical history, paraclinical data, treatment plans, and treatment outcomes. The results of two studies (using the Delphi technique) on infertility registry data in Iran (29,30) revealed that most infertility experts agreed with the design of a tool for the infertility registry system that contained medical history, treatment plant, treatment outcome, and donor information domains, and the coefficient of the agreement was greater than 75%. These results are consistent with those of the current study. Safdari et al assessed infertility registry systems and the applied tools in the system in advanced countries (e.g., Australia, US, UK, and Japan) and compared them with infertility clinical data in Iran to offer the most efficient strategies for designing a national infertility registry system in the country. They proposed a tool that contained three main domains with their relevant sub-sections. The first domain consisted of demographic data of infertile couples. The second one encompassed particular medical data including menstruation, intercourse, infertility history, medical history, history of surgery, and drug use. The last domain included causes of infertility, laboratory tests, and treatment plans (31). These results are in line with the findings of the present study. The proposed sections in the study by Safdari et al are consistent with different parts of the designed tool in the present study. This finding may indicate that the tailored questionnaire in this study could summarize important parts of medical history in infertile couples and could be repeatedly used accordingly. It also seems that this questionnaire, which has different domains, could cover all relevant information domains, and this may be positive in the results leading to pregnancy.

The reliability coefficients of the whole questionnaire and its two domains (medical history and treatment plans) were higher than the acceptable value. Nonetheless, a larger sample size is needed to increase the reliability of the other two domains. Based on the results of this study, the researchers conclude that using this questionnaire can provide physicians with high accuracy information due to its high reliability. In this regard, Mobaraki-Asl et al (17) point out that the higher the reliability of the whole tool and the reliability of each of its items, the more can be cited, and the results of the present study are in line with their results.

Limitations

The main limitation of this study was the lack of the assessment of construct validity that required larger sample sizes and factor analysis that should be addressed in future studies.

Suggestions for Future Studies

Considering the increasing number of infertile couples worldwide, it seems that developing a comprehensive national infertility database registry system using a valid and reliable tool is one of the most important requirements of each country including Iran.

This registry system has several advantages as follows:

1. It can help fertility health providers to better understand the assisted reproductive treatments and their role in preventing infertility and appropriate management of infertile couples.
2. It assists infertility specialists to make convenient decisions for treatment.
3. It can be helpful for infertility experts to provide

optimal care.
4. This system can be used to assess the effectiveness of assisted reproductive treatments and provide basic information to healthcare policymakers for planning and organizing proper national infertility treatment programs.
5. Standard database registry system facilitates data collection and processing, resulting in appropriate responses to users' needs at different levels including either healthcare providers or infertile patients.
6. It helps to improve the quality of data, specifically in relation to the better follow-up of all established pregnancies.

In this study, a tool was designed and validated, which was required for establishing the national infertility database registry system. A review of expert opinions and completed questionnaires by them revealed that this tool is suitable for collecting the data of infertile couples in the comprehensive registry system. The system should be launched to identify errors, offer necessary updates, and add new variables to improve the system.

Conclusions

In general, designing and validating this tool are only the completion of the first stage of the development of the national infertility database registry system. The second important task is to design and create the relevant software with statistical modules, enabling the rapid calculation of descriptive statistics with the options of graphic presentation using charts, histograms, and tables. Additionally, this software will enable defining and comparing the statistical parameters of the group(s) of patients, as well as calculating the statistical significance of differences. This capability would facilitate the analysis of accumulated data and help the users of the system when making a decision (e.g., the best option of the treatment). Finally, this software could act in a network to allow multi-access to data from different infertility centers in various cities.

Authors' Contribution

LF and STG: concept and design. AG and HSB and ST and MN: data collection and interpretation of the data. KH and NN and MV and MD and LAG and AT : performing of the study and writing of the draft. All authors read and approved the study.

Conflict of Interests

Authors declare that they have no conflict of interests.

Ethical Issues

This study has been approved by the ethics committee of Tabriz University of Medical Sciences (IR.TBZMED.REC.1397.941).

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References

1. Safdari R, Choobineh H, Rampisheh Z, Kameli ME, Vahedi Barzoki A. The need to design infertility registry in Iran. Journal of Medicine and Cultivation. 2016;25(3):119-128.
2. Wiwanitkit V. Difference in physiogenomics between male and female infertility. Andrologia. 2008;40(3):158-160. doi:10.1111/j.1439-0272.2008.00839.x
3. Mascarenhas MN, Flaxman SR, Boerma T, Vanderpoel S, Stevens GA. National, regional, and global trends in infertility prevalence since 1990: a systematic analysis of 277 health surveys. PLoS Med. 2012;9(12):e1001356. doi:10.1371/journal.pmed.1001356
4. Hardee K, Gay J, Blanc AK. Maternal morbidity: neglected dimension of safe motherhood in the developing world. Glob Public Health. 2012;7(6):603-617. doi:10.1080/17441692.2012.668919
5. Mohammad K, Ardalan A. An overview of the epidemiology of primary infertility in Iran. J Reprod Infertil. 2009;10(3):213-216.
6. Direkvand-Moghadam A, Sayehmiri K, Delpisheh A, Direkvand-Moghadam A. The global trend of infertility: an original review and meta-analysis. Int J Epidemiol Res. 2014;1(1):35-43.
7. Warner L, Jamieson DJ, Barfield WD. CDC releases a national public health action plan for the detection, prevention, and management of infertility. J Womens Health (Larchmt). 2015;24(7):548-549. doi:10.1089/jwh.2015.5355
8. Delpisheh A, Direkvand Moghadam A, Direkvand Moghadam F. The impact of air pollution on pregnancy outcomes: a systematic review. Iran J Obstet Gynecol Infertil. 2014;17(102):7-11. doi:10.22038/ijogi.2014.2957
9. Abara WE, Qaseem A, Schillie S, McMahon BJ, Harris AM. Hepatitis B vaccination, screening, and linkage to care: best practice advice from the American College of Physicians and the Centers for Disease Control and Prevention. Ann Intern Med. 2017;167(11):794-804. doi:10.7326/m17-1106
10. Feldman SS, Buchalter S, Hayes LW. Health information technology in healthcare quality and patient safety: literature review. JMIR Med Inform. 2018;6(2):e10264. doi:10.2196/10264
11. Ménézo YJ, Veiga A, Pouly JL. Assisted reproductive technology (ART) in humans: facts and uncertainties. Theriogenology. 2000;53(2):599-610. doi:10.1016/s0093-691x(99)00260-5
12. Ogden CL, Kuczmarski RJ, Flegal KM, et al. Centers for Disease Control and Prevention 2000 growth charts for the United States: improvements to the 1977 National Center for Health Statistics version. Pediatrics. 2002;109(1):45-60. doi:10.1542/peds.109.1.45
13. Saboktakin L, Barzegar M, Hagh Jo A, Emamalizadeh M. Study on serum copper and zinc level of children with epilepsy during long term therapy with anticonvulsants. Life Sci J. 2012;9(4):1250-54.
14. Toner JP, Coddington CC, Doody K, et al. Society for Assisted Reproductive Technology and assisted reproductive technology in the United States: a 2016 update. Fertil Steril. 2016;106(3):541-546. doi:10.1016/j.fertnstert.2016.05.026
15. Asadi F, Jahangiri Mirshekarlou S, Rahimi F. A comparative study of the national infertility registry system and the proposed model for Iran. Crescent J Med Biol Sci. 2019;6(3):318-324.
16. Khanbabayi Gol M, Dorosti A, Montazer M. Design and psychometrics cultural competence questionnaire for health promotion of Iranian nurses. J Educ Health Promot. 2019;8:155. doi:10.4103/jehp.jehp_367_18
17. Mobaraki-Asl N, Ghavami Z, Khanbabayi Gol M. Development and validation of a cultural competence questionnaire for health promotion of Iranian midwives. J Educ Health Promot. 2019;8:179. doi:10.4103/jehp.jehp_185_19
18. Thoma ME, Boulet S, Martin JA, Kissin D. Births resulting from assisted reproductive technology: comparing birth certificate and National ART Surveillance System Data, 2011. Natl Vital Stat Rep. 2014;63(8):1-11.
19. Khanbabayi Gol M, Dadashzadeh M, Mohammadipour Anvari H. Design and implementation of a checklist for prediction of anesthesia-induced nausea and vomiting in candidate patients for mastectomy. Int J Womens Health Reprod Sci. 2020;8(1):90-94. doi:10.15296/ijwhr.2020.13

20. Jain S, Dubey S, Jain S. Designing and validation of questionnaire. Int Dent Med J Adv Res. 2016;2(1):1-3. doi:10.15713/ins.idmjar.39
21. Kim GW. The Effects of Tea Meditation Program on Mindfulness, Stress and Psychological Well-Being of Middle-Aged Women with Depression [thesis]. Kyungsung University; 2012.
22. Newman I, Lim J, Pineda F. Content validity using a mixed methods approach:its application and development through the use of a table of specifications methodology. J Mix Methods Res. 2013;7(3):243-260. doi:10.1177/1558689813476922
23. Downing SM. Reliability: on the reproducibility of assessment data. Med Educ. 2004;38(9):1006-1012. doi:10.1111/j.1365-2929.2004.01932.x
24. Gwet KL. Handbook of Inter-Rater Reliability: The Definitive Guide to Measuring the Extent of Agreement Among Raters. Advanced Analytics LLC; 2014.
25. Aghamohamadi D, Khanbabayi Gol M. Checklist for determining severity of pain and type and dosage of analgesics administered to patients undergoing breast surgeries. Int J Womens Health Reprod Sci. 2020;8(2):227-231. doi:10.15296/ijwhr.2020.36
26. Mohammadbeigi A, Mohammadsalehi N, Aligol M. Validity and reliability of the instruments and types of measurments in health applied researches. J Rafsanjan Univ Med Sci. 2015;13(12):1153-1170.
27. Miller IW, Epstein NB, Bishop DS, Keitner GI. The McMaster family assessment device: reliability and validity. J Marital Fam Ther. 1985;11(4):345-356. doi:10.1111/j.1752-0606.1985.tb00028.x
28. Rakotonarivo OS, Schaafsma M, Hockley N. A systematic review of the reliability and validity of discrete choice experiments in valuing non-market environmental goods. J Environ Manage. 2016;183:98-109. doi:10.1016/j.jenvman.2016.08.032
29. Zahmatkeshan M, Farjam M, Mohammadzadeh N, et al. Design of infertility monitoring system: minimum data set approach. J Med Life. 2019;12(1):56-64. doi:10.25122/jml-2018-0071
30. Farzandipour M, Jeddi FR, Gilasi HR, Shirzadi D. Clinical and para clinical information needs of infertility electronic health records in Iran: a Delphi study. Acta Inform Med. 2017;25(3):163-168. doi:10.5455/aim.2017.25.163-168
31. Safdari R, Choobineh H, Rampisheh Z, Vahedi Barzoki A. Analysis of infertility electronic registration system data elements, a comparative study. Biomed Pharmacol J. 2016;9(1):323-336. doi:10.13005/bpj/943.