Clinical and Para Clinical Information Needs of Infertility Electronic Health Records in Iran: A Delphi Study

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ABSTRACT
Background: Infertility is referred to the person’s inability to conceive pregnancy after one year of intercourse without using protection. This study paved the ground for creating a complete, united, and coherent source of patients’ medical information. Materials and Methods: this is an applied research of descriptive-cross sectional type which has been carried out through qualitative – quantitative methods. The sample of the present study was 50 specialists in the field of infertility which has been chosen based on purposive sampling method. Designing the questionnaire was done based on library studies and Gathering experts’ views was done based on Delphi technique. Results: 261 items from clinical and Para clinical information of infertile patients’ electronic health records were subjected to an opinion poll by experts. During this process 223 items were accepted and 38 items have been rejected after two sessions of surveys by infertility experts. Para clinical information section consisted of 57 items that all of them have been accepted by the experts. Also, clinical information section consisted of 242 items from which 204 items were accepted and 38 items were rejected by the experts. Conclusion: existence of a structured electronic record system of infertile patients’ information leads to the integration of patients’ information, improvement of health care services and a decrease in treatment costs: all working to increase information safety. Furthermore, only essential and relevant information would be provided for the specialists and it will facilitate and direct the future infertility related studies due to the coherence, unity and relevance of the information.
Keywords: information requirement, infertility, electronic health record, Iran.

1. INTRODUCTION
Infertility is referred to the person’s inability to conceive pregnancy after one year of intercourse without using protection (1). World health organization named infertility as one of the severe problems of public health in all over the world (2). Availability of proper information can play a great role in the process of infertility treatment (3). Information assessment facilitates the selection process, as information needs are the engine of commencing the process of planning and decision making (4).

Paper based records, due to their inherent limitations, are not able to meet the growing needs of information in the field of health care (5). So, implementation of new technologies in order to have judicious utilization of information in this field has become a priority these days and developing electronic health records can be a solution to this problem (6). One should understand that obtained information from patients contact with infertility centers are of high importance. Whether the information are collected manually or electronically; if they are thorough, relevant and qualified, it can guarantee integrity of information, peoples’ trust in treatments outcomes, and researches’ proper results (7). Accordingly, paying due attention to the information needs of users and operators while designing information systems, developing a unified platform for electronic health systems (e.g. electronic health records) before implementing and using them, analysis of users’ understating of the system and their satisfaction rate can be a grantee for implementing a system and also would be essential (8).

2. AIM
This issue is of much importance because the information should be constantly tracked and recorded especially in infertile cases. Accordingly,
the present study was carried out with the aim of designing information requirements of electronic health records of infertility centers; in order to pave the ground for creating a unified, coherent, integrated and complete source of patients’ medical information which can obviate issues related to treatment, prescription, laboratory test results and medical health information.

3. MATERIALS AND METHODS

This is a descriptive-cross sectional type of inquiry which has been carried out through qualitative – quantitative methods. The sample to this study was a group of 50 experts working in the field of infertility including infertility fellowships, gynecologists, urologist, embryology PhD holders, and genetics PhD holders. They have been chosen based on purposive sampling method. Furthermore, they needed to have over 5 years experience of working in infertility centers.

The study was done in two phases of library research, for designing the questionnaire, and performing Delphi technique in order to collect experts’ opinion. In the first phase which has been done with the aim of identification of infertility centers’ information requirements, the researcher investigated forms, paper records related to infertility, texts and articles with regard to electronic health records, infertility information requirements mentioned in information data-bases, and collected information elements using content analysis approach. The extracted information elements from the first phase devised into a 5 point Likert scale questionnaire. For the sake of measuring face validity of the questionnaire, 2 experts in the field of health information management analyzed it.

The researchers had the questions analyzed by 15 experts with regard to their necessity, simplicity, explicitness, and relatedness using Lauche technique. Afterwards, CVI5 and CVR6 indices were calculated. During the process of measuring content validity, all the information elements obtained the required scientific scores and none of them were eliminated from the questionnaire. Information gathering was done by means of Delphi technique, in-person presence of the researcher, and questionnaire completion. Information gathering method was interview and after analyzing the answers, researchers revised the questionnaire based on expert opinions. Then, data elements were discussed again. Questionnaire revision and gathering experts’ opinion continued until an agreement was achieved.

Analyzing the data was done using spss 21 software package. Also, a number was assigned to each option in that “strongly disagree” was 1, “disagree” was 2, “neither agree nor disagree” was 3, “agree” was 4 and “strongly agree” was 5. The average score of each item was calculated and in each round of survey, items (information requirement items) which obtained an average score less than 3 were eliminated. Information requirement items which scores were in the range of 3 to less than 4 (3 <μ≤4) returned to the expert opinion poll phase again until a final agreement reached and they were either rejected or accepted. Likewise, information requirement items which scored 4 and more than 4 (4 <μ≤5) in the experts’ opinion poll were confirmed by the researchers.

The participation in the study was voluntarily and informed. The study was approved by the IR.KAUMS.REC research committee (code 1394.86).

| Couples test results data | No | % | Average | status |
|---------------------------|----|---|---------|--------|
| 1 FBS                     | 43 | 86%| 4.26    | Confirmed |
| 2 LH, FSH                 | 43 | 86%| 4.26    | Confirmed |
| 3 CBC                     | 43 | 86%| 4.26    | Confirmed |
| 4 blood group             | 43 | 86%| 4.56    | Confirmed |
| 5 RH                      | 43 | 86%| 4.35    | Confirmed |
| 6 HIV                     | 43 | 86%| 4.28    | Confirmed |
| 7 VDRL                    | 43 | 86%| 4.3     | Confirmed |
| 8 HBS AG                  | 43 | 86%| 4.3     | Confirmed |
| 9 HCV AB                  | 43 | 86%| 4.3     | Confirmed |
| 10 T3, T4, TSH            | 43 | 86%| 4.19    | Confirmed |
| 11 progesterone           | 43 | 86%| 4.3     | Confirmed |
| 12 estrogen               | 43 | 86%| 4.33    | Confirmed |
| 13 prolactine             | 43 | 86%| 4.35    | Confirmed |
| 14 testosterone           | 43 | 86%| 4.49    | Confirmed |
| 15 Test of tubal patency  | 43 | 86%| 4.49    | Confirmed |
| 16 Sperm-function tests   | 43 | 86%| 4.47    | Confirmed |
| 17 Antiphospholipid antibody IgM, IgG | 43 | 86%| 4.21    | Confirmed |
| 18 Anticardiolipin antibody IgM, IgG | 43 | 86%| 4     | Confirmed |
| 19 Antineuclear antibody (ANA) | 43 | 86%| 4.02    | Confirmed |
| 20 Post coital test (PCT) | 43 | 86%| 4.16    | Confirmed |
| 21 Anti-mullerian hormone test (AMH) | 43 | 86%| 4.19    | Confirmed |
| 22 BBT Table              | 43 | 86%| 4.12    | Confirmed |
| 23 POG TEST               | 43 | 86%| 4.16    | Confirmed |
| 24 AZT TEST               | 43 | 86%| 4.16    | Confirmed |
| 25 DHEAS TEST             | 43 | 86%| 4.14    | Confirmed |
| 26 CAP TEST               | 43 | 86%| 4.44    | Confirmed |
| 27 Semen Analysis and cultivation Test | 43 | 86%| 4.58    | Confirmed |
| 28 Semen Fructose test    | 43 | 86%| 4.56    | Confirmed |
| 29 Karyotype              | 43 | 86%| 4.56    | Confirmed |
| 30 Anti-sperm anti-body test | 43 | 86%| 4.56    | Confirmed |
| 31 Peroxidase             | 43 | 86%| 4.6     | Confirmed |
| 32 Semen plasma test      | 43 | 86%| 4.67    | Confirmed |
| 33 Spermgram test         | 43 | 86%| 4.6     | Confirmed |
| 34 Testing for antibodies in the blood | 43 | 86%| 4.4    | Confirmed |
| 35 Ovarian related tests  | 43 | 86%| 4.33    | Confirmed |
| 36 fungal and microbial tests of genital systems | 43 | 86%| 4.62    | Confirmed |
| 37 Chromosomal analysis   | 43 | 86%| 4.3     | Confirmed |
| 38 Date and results of test | 43 | 86%| 4.23    | Confirmed |

Gynecological imaging results

| Couples medical imaging results | No | % | Average | status |
|---------------------------------|----|---|---------|--------|
| 1 Hysteroalpingography (HSG)    | 43 | 86%| 4.53    | Confirmed |
| 2 Hysteroscopy                  | 43 | 86%| 4.58    | Confirmed |
| 3 Hysterosonography             | 43 | 86%| 4.51    | Confirmed |
| 4 Uterine sonography            | 43 | 86%| 4.53    | Confirmed |
| 5 Doppler sonography: three and four dimensional | 43 | 86%| 4.35    | Confirmed |
| 6 Abdominal and vaginal ultra-sonography | 43 | 86%| 4.49    | Confirmed |
| 7 Testicular sonography         | 43 | 86%| 4.53    | Confirmed |
| 8 Trans-rectal sonography (TRUS) | 43 | 86%| 4.47    | Confirmed |
| 9 Doppler Eco-graphy            | 43 | 86%| 4.37    | Confirmed |
| 10 cystoscopy                   | 43 | 86%| 4.42    | Confirmed |
| 11 Laparoscopy                  | 43 | 86%| 4.47    | Confirmed |
| 12 Vasectomy                   | 43 | 86%| 4.51    | Confirmed |
| 13 varicocelectomy             | 43 | 86%| 4.51    | Confirmed |
| 14 varicocelectomy             | 43 | 86%| 4.51    | Confirmed |
| 15 Endometrial biopsy           | 43 | 86%| 4.56    | Confirmed |
| 16 Tactical biopsy             | 43 | 86%| 4.56    | Confirmed |

*Electro Ejaculation* | 43 | 86%| 4.4    | Confirmed |

Table 1: The Average Scores of Experts’ Opinion on Infertile Couples Para Clinical Information in the Electronic Health Records- 2016
4. RESULTS

From 50 experts participated in the study, 43 of them (86%) agreed to cooperate in the study from which 8 participants (16.8%) were male and 35 participants (81.4) were female. Their age average was 44 years and their working experience among men was 17 years while it was 14 years among women. As far as their field of study was concerned, 6 experts (13.95%) were embryologist, 2 experts (4.65%) were genetics specialist, 34 experts (70.08%) were gynecologist, and 1 expert (2.32%) was urologist. Likewise, as far as their academic degree was concerned, 1 expert (2.32%) was specialist, 8 experts (18.6%) were PhD holders, 20 (46.52%) experts were surgeons sub-specialist in gynecology, and 14 (32.56%) experts got infertility fellowship (table 1, table 2).

| Females' current diseases history | No | % | Average status |
|----------------------------------|----|---|----------------|
| 1 Current disease                 | 43 | 86%| 4              | Confirmed       |
| 2 Treatments done for the current diseases | 43 | 86%| 4              | Confirmed       |
| 3 Age of first menstrual cycle    | 43 | 86%| 4.87           | Confirmed       |
| 4 Day, month and year of last menstrual cycle | 43 | 86%| 4.6            | Confirmed       |
| 5 The shortest/longest time interval during bleeding | 43 | 86%| 4.35           | Confirmed       |
| 6 Bleeding flow (dark or bright)  | 43 | 86%| 4              | Confirmed       |
| 7 Regular menstruation            | 43 | 86%| 4.53           | Confirmed       |
| 8 Irregular menstruation          | 43 | 86%| 4.56           | Confirmed       |
| 9 Painful menstruation (before bleeding) | 43 | 86%| 4.47           | Confirmed       |
| 10 Painful menstruation (during bleeding) | 43 | 86%| 4.51           | Confirmed       |
| 11 Rare menstruation              | 43 | 86%| 4.49           | Confirmed       |
| 12 Absence of menstruation        | 43 | 86%| 4.53           | Confirmed       |
| 13 Bleeding between menstrual cycles | 43 | 86%| 4.33           | Confirmed       |
| 14 Breast sensitivity             | 43 | 86%| 4.23           | Confirmed       |
| 15 Galactorrhea                   | 43 | 86%| 4.26           | Confirmed       |
| 16 Flaming                        | 43 | 86%| 4.23           | Confirmed       |
| 17 Pelvic pain or cramp during menstruation | 43 | 86%| 4.12           | Confirmed       |
| 18 Pelvic pain or cramp before menstruation | 43 | 86%| 4.12           | Confirmed       |
| 19 Pelvic pain or cramp after menstruation | 43 | 86%| 4.07           | Confirmed       |
| 20 Pelvic pain or cramp during urination | 43 | 86%| 4.33           | Confirmed       |
| 21 Pelvic pain or cramp during fast activities | 43 | 86%| 4.3            | Confirmed       |
| 22 List of medication used for Pelvic pain or cramp | 43 | 86%| 4.33           | Confirmed       |
| 23 Latest genital system test results and date | 43 | 86%| 4.49           | Confirmed       |
| 24 Latest pap smear result and date | 43 | 86%| 4.35           | Confirmed       |
| 25 Latest mammography result and date | 43 | 86%| 4.26           | Confirmed       |

| Male problems and diseases | No | % | Average status |
|----------------------------|----|---|----------------|
| 1 Prostate                 | 43 | 86%| 4.6            | Confirmed       |
| 2 Testicile tumor          | 43 | 86%| 4.53           | Confirmed       |
| 3 Epididymitis             | 43 | 86%| 4.51           | Confirmed       |
| 4 Orchiditis               | 43 | 86%| 4.51           | Confirmed       |
| 5 Testicle injuries        | 43 | 86%| 4.56           | Confirmed       |
| 6 Immature testicles       | 43 | 86%| 4.53           | Confirmed       |
| 7 Injuries and inflammation of urinary tracts | 43 | 86%| 4.4            | Confirmed       |
| 8 Inguinal hernia          | 43 | 86%| 4.56           | Confirmed       |
| 9 Hydrospadias             | 43 | 86%| 4.33           | Confirmed       |
| 10 Sympathectomy           | 43 | 86%| 4.33           | Confirmed       |
| 11 Hydrocoil               | 43 | 86%| 4.37           | Confirmed       |
| 12 Penile wounds           | 43 | 86%| 4.44           | Confirmed       |
| 13 Scrotal swelling        | 43 | 86%| 4.51           | Confirmed       |
| 14 Thick or thin epididymis| 43 | 86%| 4.3            | Confirmed       |
| 15 Spermatocele            | 43 | 86%| 4.42           | Confirmed       |
| 16 Varicocele              | 43 | 86%| 4.6            | Confirmed       |
| 17 Gynecomastia            | 43 | 86%| 4.42           | Confirmed       |
| 18 High fever in last six month | 43 | 86%| 4.28           | Confirmed       |
| 19 Swollen-occipital lymph node | 43 | 86%| 4.07           | Confirmed       |
| 20 Infected wounds         | 43 | 86%| 4.26           | Confirmed       |
| 21 Congenital disorders    | 43 | 86%| 4.16           | Confirmed       |
| 22 Erection problems       | 43 | 86%| 4.44           | Confirmed       |
| 23 Ejaculation problems    | 43 | 86%| 4.63           | Confirmed       |
| 24 Peris discharge         | 43 | 86%| 4.67           | Confirmed       |
| 25 Semen analysis , date of analysis and its results | 43 | 86%| 4.67           | Confirmed       |
| 26 Microscopic findings of semen analysis | 43 | 86%| 4.63           | Confirmed       |
| 27 other performed tests, date and results | 43 | 86%| 4.16           | Confirmed       |

| Males’ case history | No | % | Average status |
|--------------------|----|---|----------------|
| 1 Duration of marriage in Day, month and year | 43 | 86%| 4.07           | Confirmed       |
### Table 2. The Average Scores of Experts’ Opinion on Infertile Couples’ Clinic Information in the Electronic Health Records - 2016

| No | Disease/Procedure                                      | No % | Average status |
|----|-------------------------------------------------------|------|----------------|
| 1  | Couples’ parental history                             | No   | Average status |
| 2  | Breast/ Ovarian / Intestine / Uterus / Cervix / Endometriosis cancer | 43   | 4.63           |
| 3  | Diabetes                                              | 43   | 4.47           |
| 4  | Cardio vascular diseases                              | 43   | 4.47           |
| 5  | High and low blood pressure                           | 43   | 4.47           |
| 6  | Auto immune disorders                                 | 43   | 4.47           |
| 7  | Blood disorders like Thalassemias and Hemophilia      | 43   | 4.47           |
| 8  | Spine Bifida                                          | 43   | 4.47           |
| 9  | Anencephaly                                           | 43   | 4.47           |
| 10 | Muscular dystrophy                                    | 43   | 4.47           |
| 11 | Cystic-pharoses                                       | 43   | 4.47           |
| 12 | Huntington                                            | 43   | 4.47           |
| 13 | Infertility                                           | 43   | 4.47           |
| 14 | Repetitive abortion                                   | 43   | 4.47           |
| 15 | Premature ovanian failure and Irregular menstration cycles | 43 | 4.47           |
| 16 | Congenital deficits like Cleft lips                   | 43   | 4.47           |
| 17 | Chromosome disorders                                  | 43   | 4.47           |
| 18 | Autism                                                | 43   | 4.47           |
| 19 | Every important family history                        | 43   | 4.47           |
| 20 | A list of people with mentioned problems in the family | 43   | 4.47           |
| 21 | Couples’ consultation                                 | No   | Average status |
| 22 | Infertility consultation                              | 43   | 4.47           |
| 23 | Physiologic consultation                              | 43   | 4.47           |
| 24 | Genetic consultation                                  | 43   | 4.47           |
| 25 | Urologic consultation                                 | 43   | 4.47           |
| 26 | Couples’ infertility diagnosis                        | No   | Average status |
| 27 | Couples’ treatments                                   | No   | Average status |
| 28 | ICSI                                                  | 43   | 4.47           |
| 29 | IVF                                                   | 43   | 4.47           |
| 30 | IUI                                                   | 43   | 4.47           |
| 31 | GIFT                                                  | 43   | 4.47           |
| 32 | ZIFT                                                  | 43   | 4.47           |
| 33 | Blastocyst Transfer                                   | 43   | 4.47           |
| 34 | Assisted Hatching                                     | 43   | 4.47           |
| 35 | Egg Donation                                          | 43   | 4.47           |
| 36 | Sperm Donation                                        | 43   | 4.47           |
| 37 | THE FROZEN EMBRYO REPLACEMENT CYCLE (F ERC)            | 43   | 4.47           |
| 38 | 11 Ovulation induction                                | 43   | 4.47           |
| 39 | 12 Surrogacy                                          | 43   | 4.47           |
| 40 | 13 Drug therapy                                       | 43   | 4.47           |
| 41 | 14 Surgery                                            | 43   | 4.47           |
| 42 | 15 Date and results of performed treatments            | 43   | 4.47           |
| 43 | 16 Procedure explanation                             | 43   | 4.47           |
| 44 | 17 List of medications                                | 43   | 4.47           |

### 5. DISCUSSION

The present study included 261 clinic and Para clinic information items from infertile patients’ electronic health re-
cords that has been subjected to a poll for infertility experts’ opinion. The opinion poll results showed that 223 information items were accepted and 38 items (after two phases of polling) were rejected based on infertility experts’ opinion.

**Para clinical information**

In this section, experts voted for 57 information items and all of them were acceptable to them. In order to achieve pregnancy, the couple should be sound and healthy; therefore, the results of Para clinical interventions determine the couples’ fertility levels and the quality of follow up treatment procedures. Accordingly, it has been considered as the most important way of diagnosing the causes of infertility.

Kahouei et al. (2013), in accordance with the present study, reported that presence of different types of Para clinical information in electronic health records is of crucial importance and these information can change the process of clinical interventions. It also can help to improve the quality of medical care delivered to the patients (9).

In Nikbakt et al.’s study, Hysteroscopy has been assessed of higher importance over Hysterosalpingography during checking uterine cavity. Even when Hysterosalpingography is normal, Hysteroscopy can improve diagnosis up to 40%. Due to the ease of performance, it is suggested that Hysteroscopy should be a part of the routine checking process of infertile couples (10). This is also in accordance with the results of the current study.

**Clinical information**

In this section the total number of 242 information items was subjected to the experts’ opinion poll. As a result, 204 information items were accepted and 38 items were rejected. One of the most crucial information items in the process of infertile patients’ treatment is drugs’ side effects and allergies. This area has also been chosen as an important information item by infertility experts. Different studies emphasized on the importance of this issue as well.

Bonde’s study in line with the present study indicates that patients who are dealing with chemical materials are suffering from infertility more than other people (11). Smoking also can be related to the male infertility. Studies indicated that intercourse rate in non smoker people is twice as many as smokers and smoking can affect sperms quality with their form and motility (12).

**Varicocele**, vaginal infection and testicular damage has been mentioned as the most common reasons of male infertility (13-14), a fact which is in accordance with the results of the present study. Based on safdari et al., length of infertility and marriage duration are two important infertility information items. Besides, recording these items in patients’ electronic health records has been assessed as of crucial importance (15).

One of the necessary factors in infertility electronic records is menstrual cycle with its regularity, painfulness, time length, bleeding between cycles and breast sensitivity. It is proven that recording this information can be highly effective in the treatment process. Also these information items were considered important in Australian, American and British electronic record systems (16-17). Abortion and miscarriage, ectopic pregnancy, molar pregnancy, and tubal pregnancy were also among the important information items according to Iranian infertility experts. These items are also recorded in American and Australian electronic record systems (16-17).

In present study, family history was mentioned as an important information category. We believe that most infertility problems and disorders can be traced back to the patients’ family history and discovering these patterns can contribute to the treatment process of infertile couples. Noticing and recording information like repeated abortions, infertility, genetic diseases of couples, genetic diseases of other children, genetic disorders, person’s medical history in patients’ electronic health records is highly necessary; whilst in ahmadi et al.’s study, family history and congenital disorders achieved the least mean score (18).

In their study, Dayan et al. stated that electronic health records through decreasing expenses and improving incomes can be even financially beneficial to the patients and medical organizations. In conclusion, “cost-savings programs exist, but computerization, which allows them to be implemented in a highly effective manner, is an excellent platform for economic efficiency” (19).

6. **CONCLUSION**

Nowadays, in current society, infertility is among the most serious issues of life and has a great effect on families and society mental health. Existence of a developed and systematic electronic health record system for infertile patients can cause integrity of patients’ information, improvement of medical care, reduction of medical costs, increasing information safety, delivery of only crucial and related information to the specialists, and also facilitates future infertility researches due to collection of coherent, integrated and related information. To reach the above mentioned aims, the present study shed some lights on information items of infertility centers’ electronic health records based on infertility experts opinions in two sections clinical and Para clinical.

- **Conflict of interest:** We have no conflicts of interest to disclose.
- **Author contribution:** Mehrdad Farzandipour and Diana Shirzadi conceived of the presented idea. Diana Shirzadi developed the theory and performed the computations. Hamid Reza Gilasi and Fatameh Rangraz Jeddii verified the analytical methods. Mehrdad Farzandipour encouraged Diana Shirzadi to investigate the subject and supervised the findings of this work. All authors discussed the results and contributed to the final manuscript.

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Clinical and Para Clinical Information Needs of Infertility Electronic Health Records in Iran: A Delphi Study

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