Health Information Technology Department
Mashhad University of Medical Sciences

In the name of God

Mashhad University of
Medical Sciences

The Development of a Minimum Data Set for an Infertility Registry

Lecturer Name: Alireza Banaye Yazdipour

Supervisor Name: Dr. Khalil Kimiafar

Email Address: yazdipoura961@mums.ac.ir

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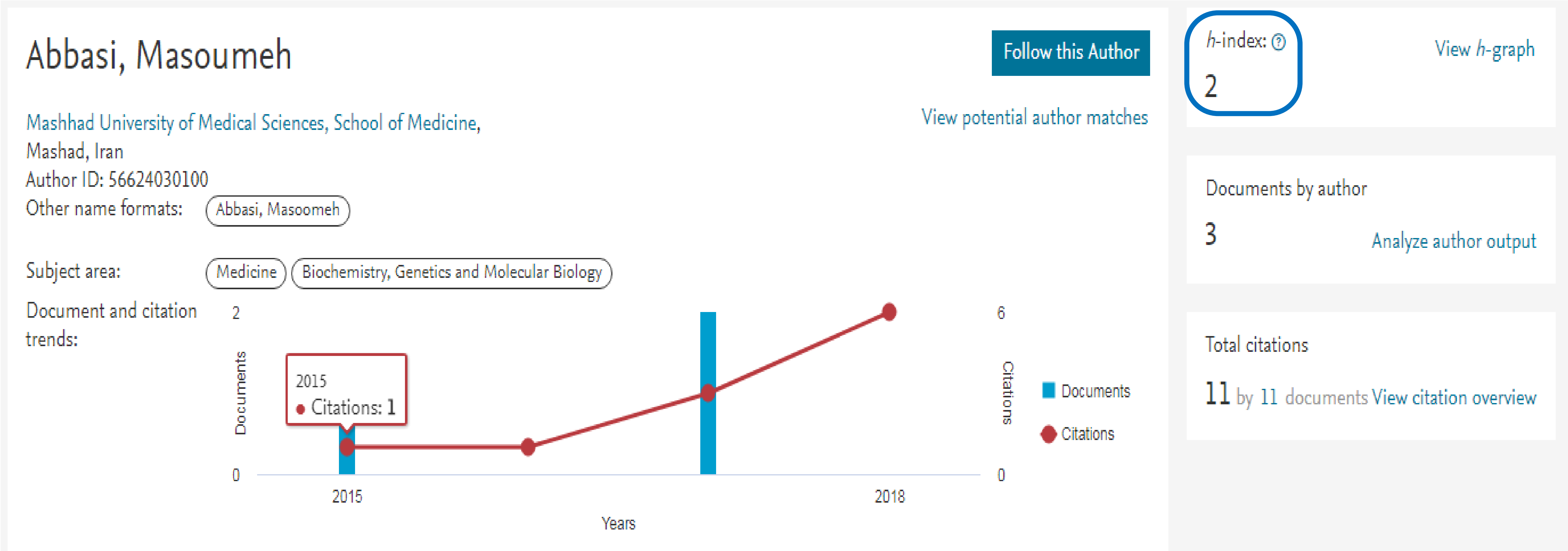
Author's Information

- Dr. Masoumeh Abbasi
- Medical Informatics Specialist (Ph.D)
- Responsible for the registry of diseases in Kermanshah University of Medical Sciences

Corresponding author



Abbasi, Masoumeh

Mashhad University of Medical Sciences, School of Medicine,
Mashad, Iran
Author ID: 56624030100
Other name formats: Abbasi, Masoumeh

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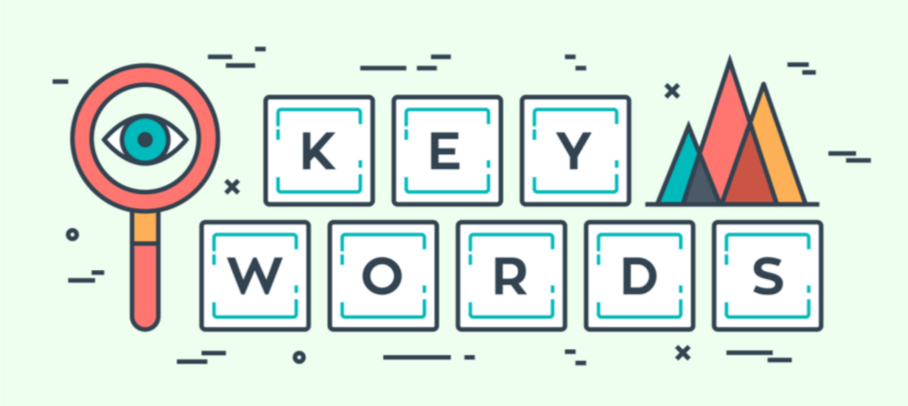


Introduction and Background

- **Infertility** is a considerable **health challenge** in **developing countries** [1] and is associated with poor **mental** and **social outcomes** [2].
- **Depression**, **fear of divorce**, **remarriage**, **high treatment costs**, and **fear of uncertainty about the treatment outcomes** are just some of the **challenges** that people who are suffering from **infertility** experience [3-6].
- According to the **World Health Organization** (WHO), **one in four** married couples in **developing countries** encounter **infertility problems** [7]. In **Iran**, fertility problems are experienced by **20.2** percent of couples [8].

Introduction and Background

- A range of **therapeutic methods** of **treating infertility** are available, such as:

- intrauterine insemination (IUI)
- in vitro fertilization (IVF)
- intracytoplasmic sperm injection (ICSI)
- and their application varies according to the **cause of infertility**.

Introduction and Background

- Various **models** have been created to **predict** the likelihood of a **successful pregnancy** following **medical intervention** [9].
- When **creating a predictive model**, it is important to **ensure** that the **data** are **accurate**, **complete**, and **aligned** with the **clinical goals** [10].
- **Decision makers** who are responsible for the implementation of **clinical** and **managerial healthcare policy** rely on the **availability** of **data** and key **information** [11].

Introduction and Background

- A **minimum data set** is recommended as a **standard tool** that can guide **data collection.**
- A **minimum data set** is a **structure of information** that is collated from **different sources** and is developed using **definitions** and **procedures**.
- This information facilitates the **creation of a comprehensive database** on a particular subject.
- A **minimum data set** can be used to healthcare services in **hospitals**, **nursing houses**, and **healthcare institutions**.
- The **recording of patient data elements** **improves the quality of healthcare** and **decreases costs** [16].

Introduction and Background

- To the best of our knowledge, a **minimum data set** has not yet been developed for infertility in **Iran**.
- The objective of the current study was to **develop a minimum data set for infertility** as a means of establishing an **infertility registry** in Iran that could expedite the **collection of reliable and detailed data** from patients who have been referred to infertility centers.

Methods

- This **descriptive**, **cross-sectional** study was conducted in **2016**. The **infertility minimum data set** was developed via a **four-stage** process:

- 1. Systematic review
- 2. Classification of the data elements
- 3. Validation of the data elements using the Delphi technique
- 4. Determination of the accessibility of data elements using focus group discussion

Methods

1- Systematic Review

- A systematic review was conducted using sources from the **PubMed**, **ScienceDirect**, **Scopus**, **Embase**, **Web of Science**, **IEEE Xplore**, and **Google Scholar** databases.

Methods

1- Systematic Review

- A keyword search of these databases was performed using words related to the concepts of *minimum data set* or *infertility registry* (**dataset, dataset as topic, common data element, registries**, minimum dataset)
- Keywords relating to *infertility* (**in vitro fertilization, artificial insemination**, intrauterine insemination, **intracytoplasmic sperm injections, assisted reproductive technique, infertility**).
- Keyword MeSH terms are shown in bold.
- The websites of infertility institutions were also searched for patient forms.

Methods

1- Systematic Review

- Both searches were performed in the **second week of June 2016**.
- Databases were screened for **English articles** only without any limitation on **time** and **type of study**.
- The **keywords** and **references of the articles** identified during the initial search were also considered as a means of identifying additional keywords and other relevant articles (see Table 1).

Methods

1- Systematic Review

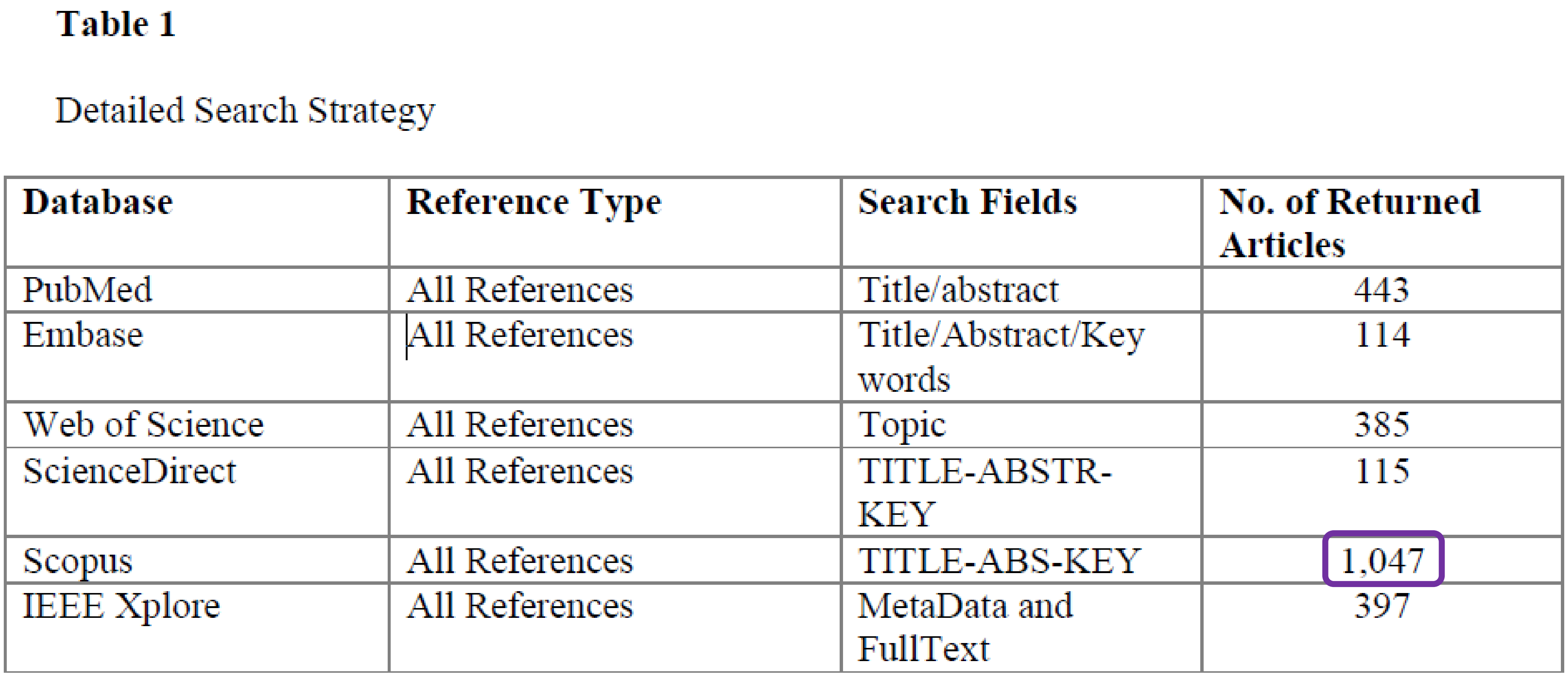


Table 1

Detailed Search Strategy

Database	**Reference Type**	**Search Fields**	**No. of Returned Articles**
PubMed	All References	Title/abstract	443
Embase	All References	Title/Abstract/Key words	114
Web of Science	All References	Topic	385
ScienceDirect	All References	TITLE-ABSTR-KEY	115
Scopus	All References	TITLE-ABS-KEY	1,047
IEEE Xplore	All References	MetaData and FullText	397

Methods

1- Systematic Review

- The electronic database **search** was performed by **one reviewer**.

- The **titles** and **abstracts of all articles** were screened by **two reviewers** to identify articles that were relevant to the research objectives. One of these reviewers was the same person who conducted the initial database search.

- The **full text of the articles** was then assessed to ensure that the **inclusion and exclusion criteria** for the study were met.

Methods

1- Systematic Review

- **Data extraction** was facilitated with the use of **a checklist** that contained the **study objectives**, **setting**, **type of study**, **data sources**, **data collection methods** (computer- or paper-based), **main classification**, and **data elements**.
- **Patient forms** were downloaded from the **websites of the infertility institutions**.
- The **data elements** were **extracted** from the **forms** and **related articles**, and **duplicate** items were **deleted**.

Methods

1- Systematic Review

- The inclusion criterion were **all articles** published in **English** that focused on the **establishment of infertility registries** and the **development of an infertility minimum dataset**, and **patient forms** from infertility institutions.
- Studies that reported **registry data analysis without identifying the data elements** were **excluded**.
- **Seminar abstracts**, **letters to the editor**, **theses**, **dissertations**, and **position papers** were also **excluded**.

Methods

2- Classification of the Data Elements

- The **articles identified** during the **first stage** of the research employed **various classifications of the data elements**.
- Therefore, the **classification** applied to the **extracted data elements** was determined via **separate two-hour meetings** with **three infertility experts**.
- With all three experts' opinions taken into account, any **classifications** that the **experts** believed were **not practical** were **omitted**.

Methods

3- Validation of the Data Elements Using the Delphi Technique

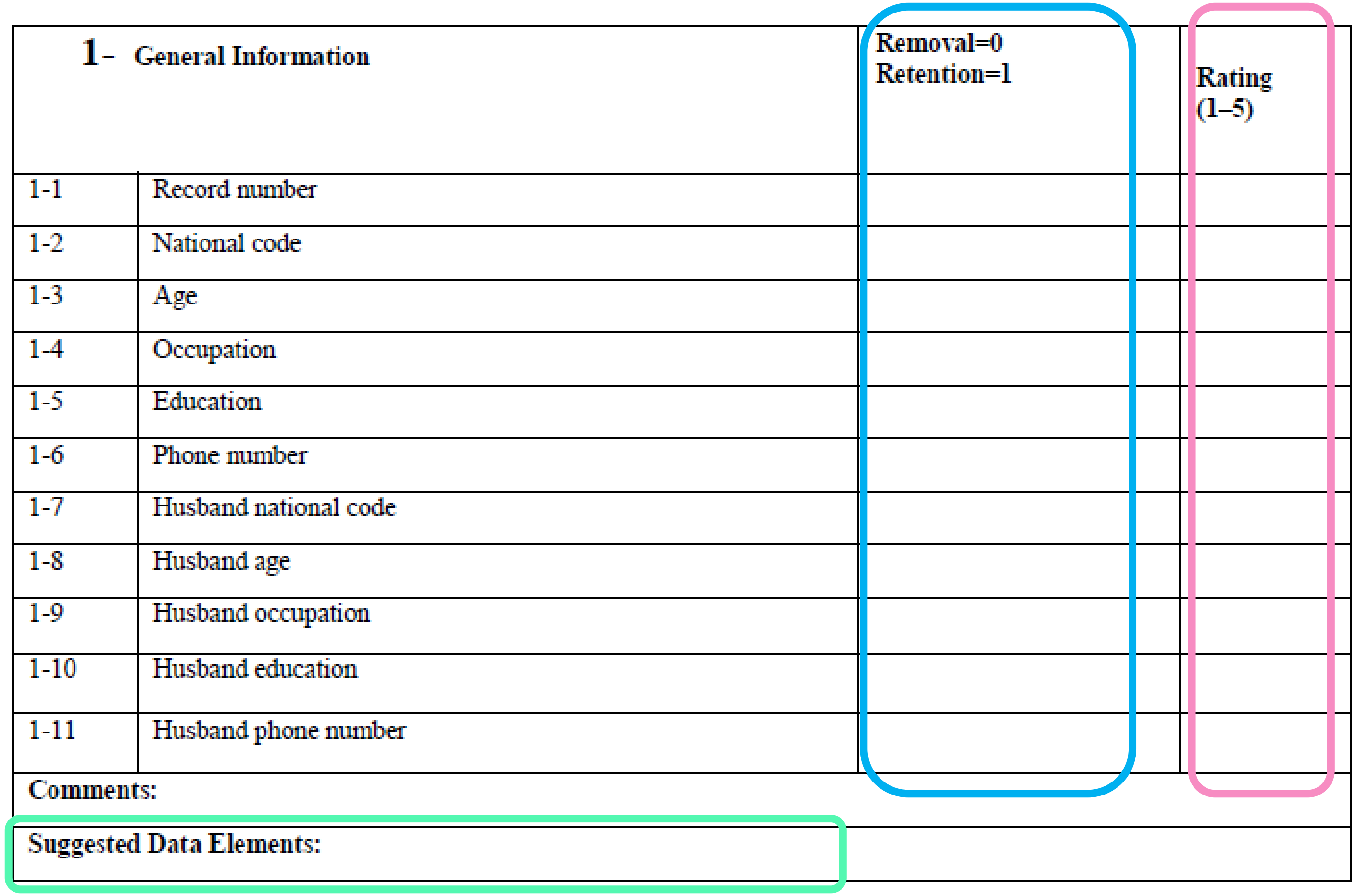
- The **data elements** were **validated** using **two rounds** of the **Delphi technique**.
- **A two-column checklist** was developed for the **first round**.
- The **first column** recorded whether **each data element** would be **deleted** or **retained** from the **data set**, while the **second column** the item according to the **degree of importance** based on a **five-point Likert scale**, ranging from **low importance (1)** to **high importance (5)**. At the **end of each classification**, a **row** was provided for the **data elements suggested** by the **experts** (see Appendix 1).

Appendix 1

Delphi Technique Checklist Round 1

First column:
deleted or retained

Second column:
degree of importance



1- General Information		**Removal=0** **Retention=1**	**Rating (1–5)**
1-1	Record number		
1-2	National code		
1-3	Age		
1-4	Occupation		
1-5	Education		
1-6	Phone number		
1-7	Husband national code		
1-8	Husband age		
1-9	Husband occupation		
1-10	Husband education		
1-11	Husband phone number		
Comments:			
Suggested Data Elements:			

Data elements suggested
experts

Methods

3- Validation of the Data Elements Using the Delphi Technique

- The **concept of a minimum data set** was **explained** to the **participants**, and they were asked to **score** the **checklist elements** based on the following question: “Do you think this data element is essential for an evaluation of an infertility patient’s therapeutic status and to make a decision as to the appropriate treatment intervention?”.

Methods

3- Validation of the Data Elements Using the Delphi Technique

- The **level of agreement** was considered to be a **criterion for the acceptance of the data elements**.
- **Elements** that were **scored 4 or 5** by at **least 50 percent of the experts** were considered for **inclusion** in the **minimum data set**.
- **Elements** that received a **score** of **1 or 2** from at **least 50 percent of the experts** were **excluded**.
- The **remaining elements** were entered into the **second round of the Delphi technique**.

Methods

3- Validation of the Data Elements Using the Delphi Technique

- The **same checklist** that was used in the **first round of the Delphi technique** was used in the **second round** with one **minor change**: the **data element suggestion row** was **removed**.
- The **results** of the **first-round analysis** were given to the **experts**, and they were asked to determine the **score** for each **data element listed in the checklist**.
- **Similar** to the procedure followed in **round 1**, **elements** that received a **score of 4 or 5** by at **least 50 percent of the experts** were considered for **inclusion** in the **minimum data set**.
- The **remaining elements** were **disregarded**.

Methods

3- Validation of the Data Elements Using the Delphi Technique

- Each round of the Delphi technique lasted **four weeks**.
- Both **checklists** were presented to the **experts in person**.
- The **experts** were **blind** to the given by the **other experts**.

Methods

4- Accessibility of Data Elements Using Focus Group Discussion

- To evaluate the **accessibility** of the proposed minimum data set, a **focus group** discussion was held with **five experts** as a means of obtaining their **opinions** on the **recommended** minimum data set.
- This session lasted **two hours**.
- The **focus group** provided the **experts** with an opportunity to **discuss** and **compare experiences** [19].

Results

1- Systematic Review

- A total of **2,501** articles were obtained from different databases.
- After we **excluded** **duplicate articles** and reviewed the **titles and abstracts** of those initially identified, **66 articles** were selected for the **final survey**.
- After the application of the study **inclusion and exclusion criteria**, **10 of these articles** were considered for **extraction of data elements**.
- **A further article** was identified during an **evaluation of the references** contained in the shortlisted articles [20] however, it did **not** meet the **inclusion criteria**.

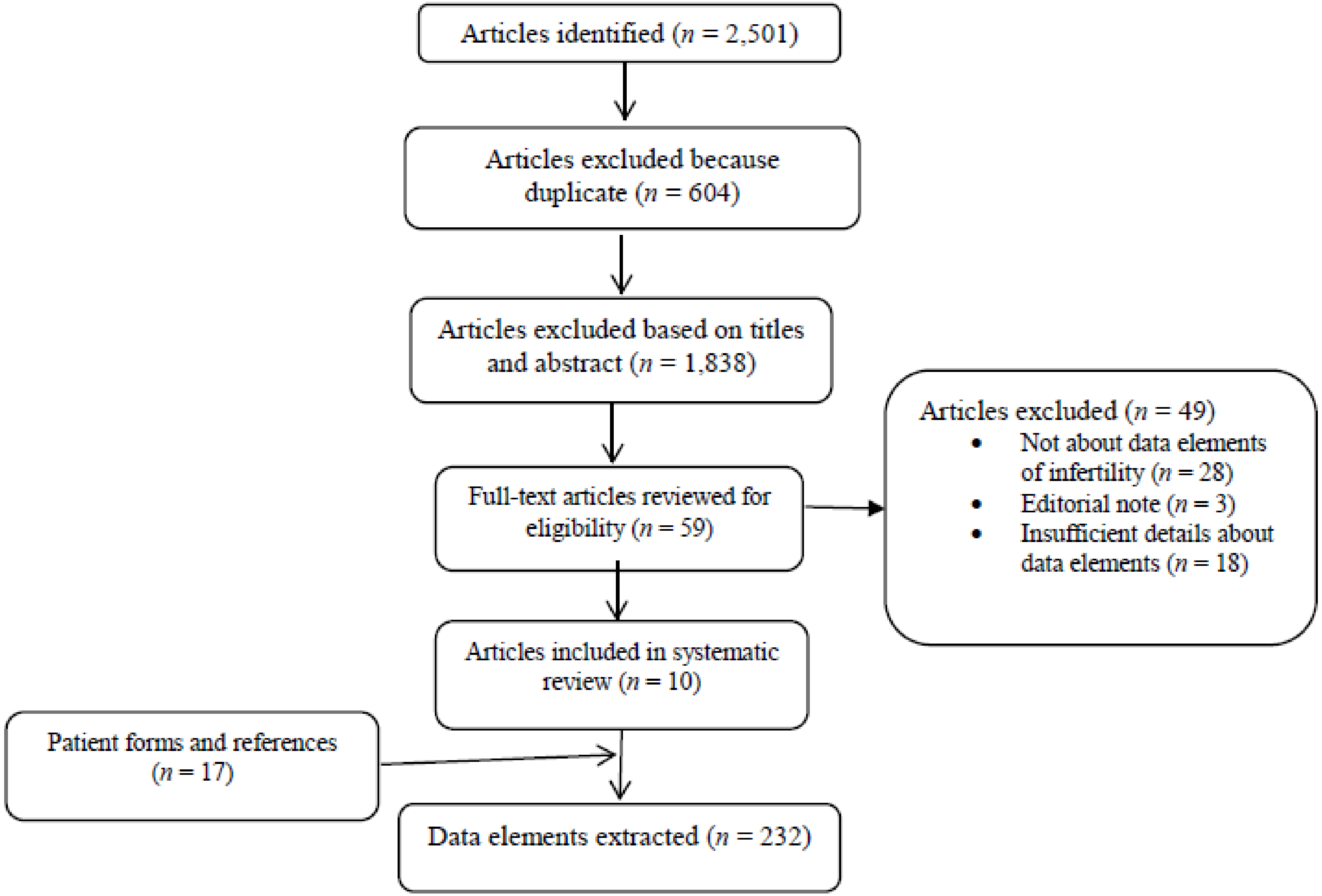
Results

1- Systematic Review

- A total of **17 patient forms** were extracted from **infertility centers websites**.
- The patient form search continued until **no new data elements** were identified.
- A total of **232 data elements** were identified on the **forms** and within the shortlisted **articles**.

Figure 1

Systematic Review Flowchart



Articles identified ($n = 2{,}501$)

Articles excluded because duplicate ($n = 604$)

Articles excluded based on titles and abstract ($n = 1{,}838$)

Full-text articles reviewed for eligibility ($n = 59$)

Articles excluded ($n = 49$)
- Not about data elements of infertility ($n = 28$)
- Editorial note ($n = 3$)
- Insufficient details about data elements ($n = 18$)

Articles included in systematic review ($n = 10$)

Patient forms and references ($n = 17$)

Data elements extracted ($n = 232$)

The **characteristics** of the **10** included articles are summarized in Table 2.

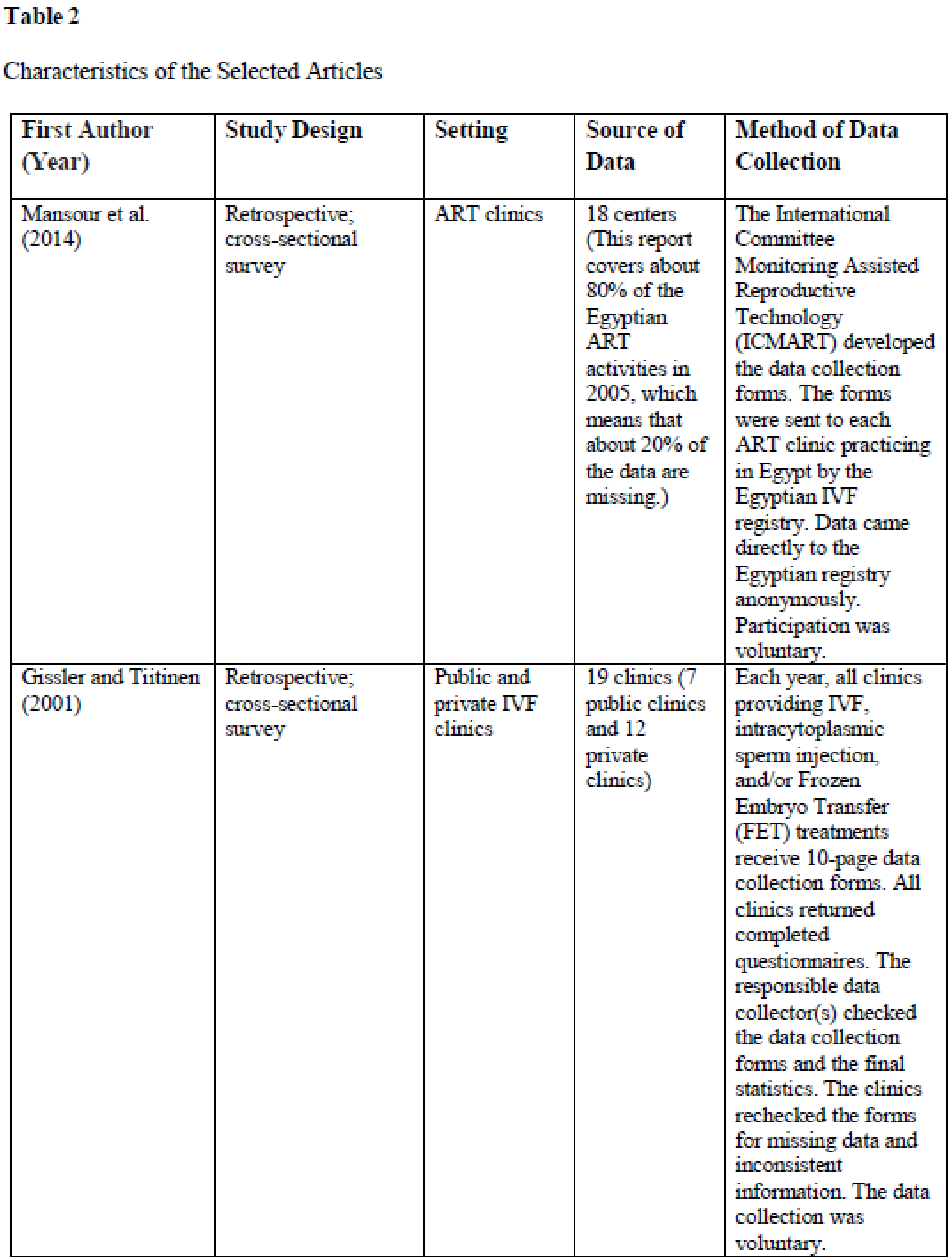


Table 2

Characteristics of the Selected Articles

First Author (Year)	Study Design	Setting	Source of Data	Method of Data Collection
Mansour et al. (2014)	Retrospective; cross-sectional survey	ART clinics	18 centers (This report covers about 80% of the Egyptian ART activities in 2005, which means that about 20% of the data are missing.)	The International Committee Monitoring Assisted Reproductive Technology (ICMART) developed the data collection forms. The forms were sent to each ART clinic practicing in Egypt by the Egyptian IVF registry. Data came directly to the Egyptian registry anonymously. Participation was voluntary.
Gissler and Tiitinen (2001)	Retrospective; cross-sectional survey	Public and private IVF clinics	19 clinics (7 public clinics and 12 private clinics)	Each year, all clinics providing IVF, intracytoplasmic sperm injection, and/or Frozen Embryo Transfer (FET) treatments receive 10-page data collection forms. All clinics returned completed questionnaires. The responsible data collector(s) checked the data collection forms and the final statistics. The clinics rechecked the forms for missing data and inconsistent information. The data collection was voluntary.

Results

2- Classification of the Data Elements

- The potential **participants** consisted of **19 gynecologists** and **infertility experts** from **two private infertility centers** and **one academic infertility center**. However, **six** gynecologists and infertility experts **did not participate** in the study. Thus, **13 experts** contributed.
- Of these, all **13** (68 percent) participated in the **first round of the Delphi survey**, and **nine** (47 percent) participated in the **second round**.
- During the sessions with **three experts**, **five classifications** were identified: **General Information**, **Patient History**, **Paraclinical Reports**, **Treatment Plan** (IVF/ICSI, IUI, IO), and **Treatment Outcome**.
- The **Lifestyle** and **Psychological classifications**, in addition to their data elements (20 of the 232 data elements), were **removed** on the basis of the experts' opinions.

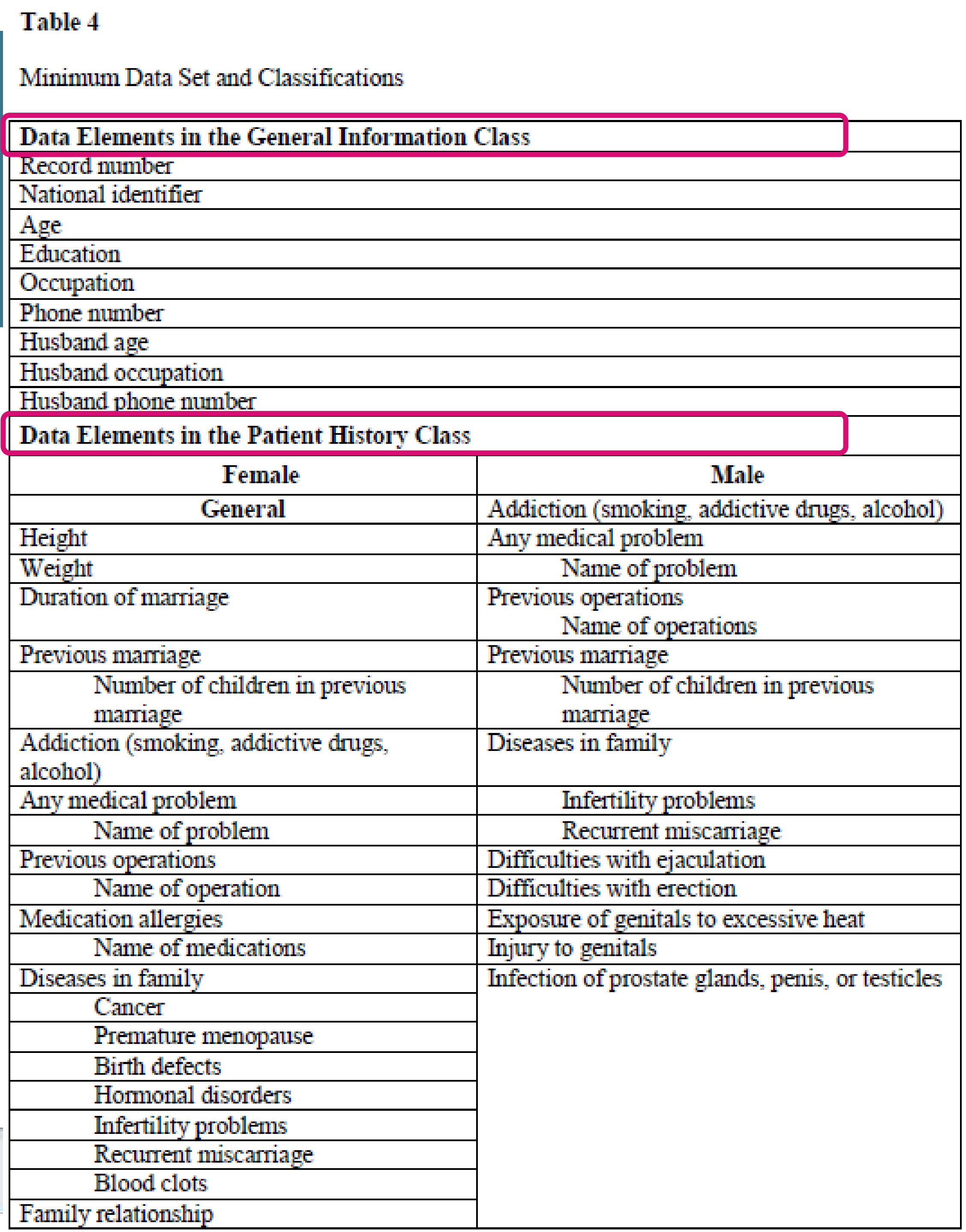


Table 4

Minimum Data Set and Classifications

Data Elements in the General Information Class
Record number
National identifier
Age
Education
Occupation
Phone number
Husband age
Husband occupation
Husband phone number

Data Elements in the Patient History Class

Female	**Male**
General	Addiction (smoking, addictive drugs, alcohol)
Height	Any medical problem
Weight	Name of problem
Duration of marriage	Previous operations Name of operations
Previous marriage	Previous marriage
Number of children in previous marriage	Number of children in previous marriage
Addiction (smoking, addictive drugs, alcohol)	Diseases in family
Any medical problem	Infertility problems
Name of problem	Recurrent miscarriage
Previous operations	Difficulties with ejaculation
Name of operation	Difficulties with erection
Medication allergies	Exposure of genitals to excessive heat
Name of medications	Injury to genitals
Diseases in family	Infection of prostate glands, penis, or testicles
Cancer	
Premature menopause	
Birth defects	
Hormonal disorders	
Infertility problems	
Recurrent miscarriage	
Blood clots	
Family relationship	

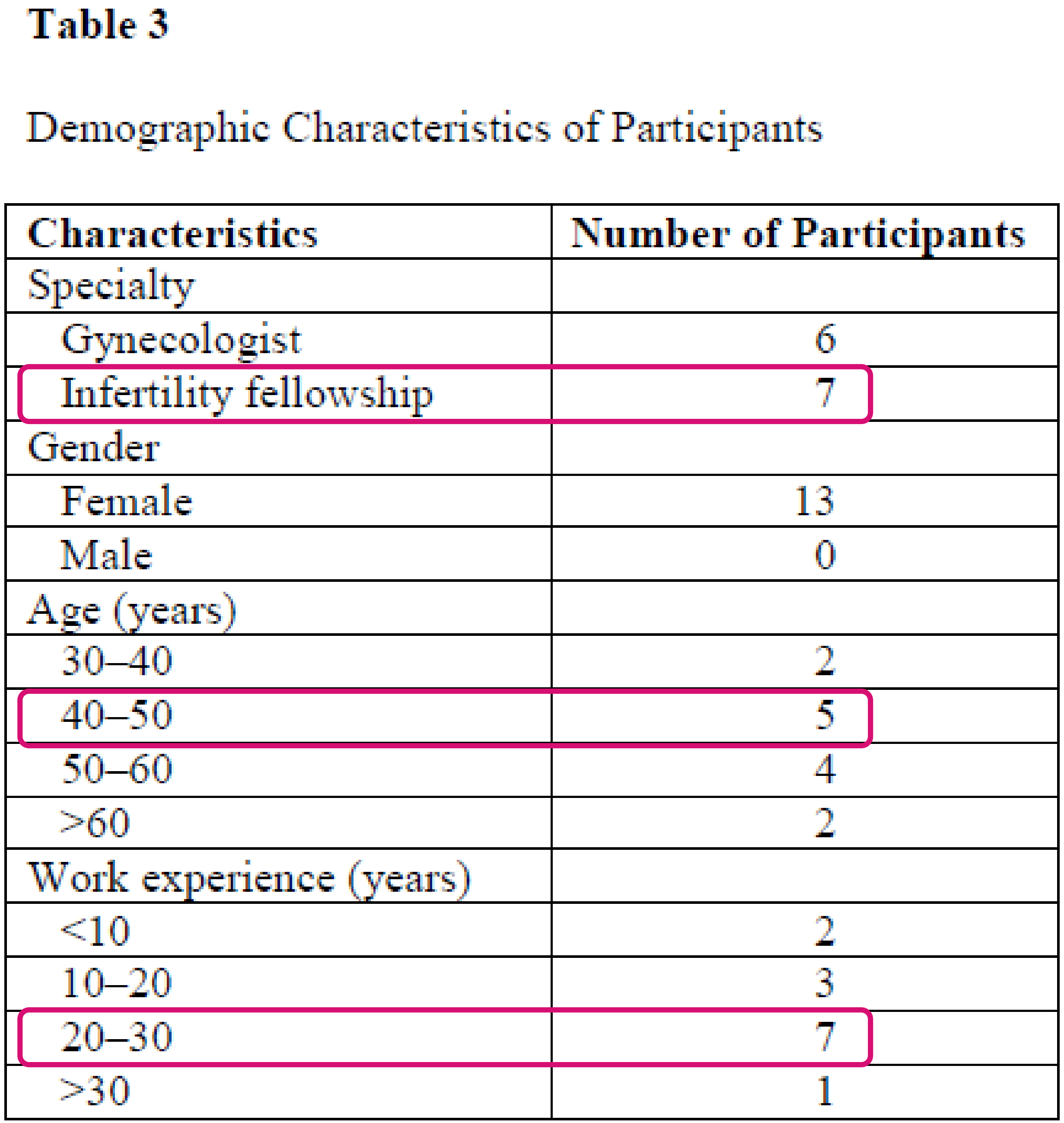


Table 3

Demographic Characteristics of Participants

Characteristics	Number of Participants
Specialty	
Gynecologist	6
Infertility fellowship	7
Gender	
Female	13
Male	0
Age (years)	
30–40	2
40–50	5
50–60	4
>60	2
Work experience (years)	
<10	2
10–20	3
20–30	7
>30	1

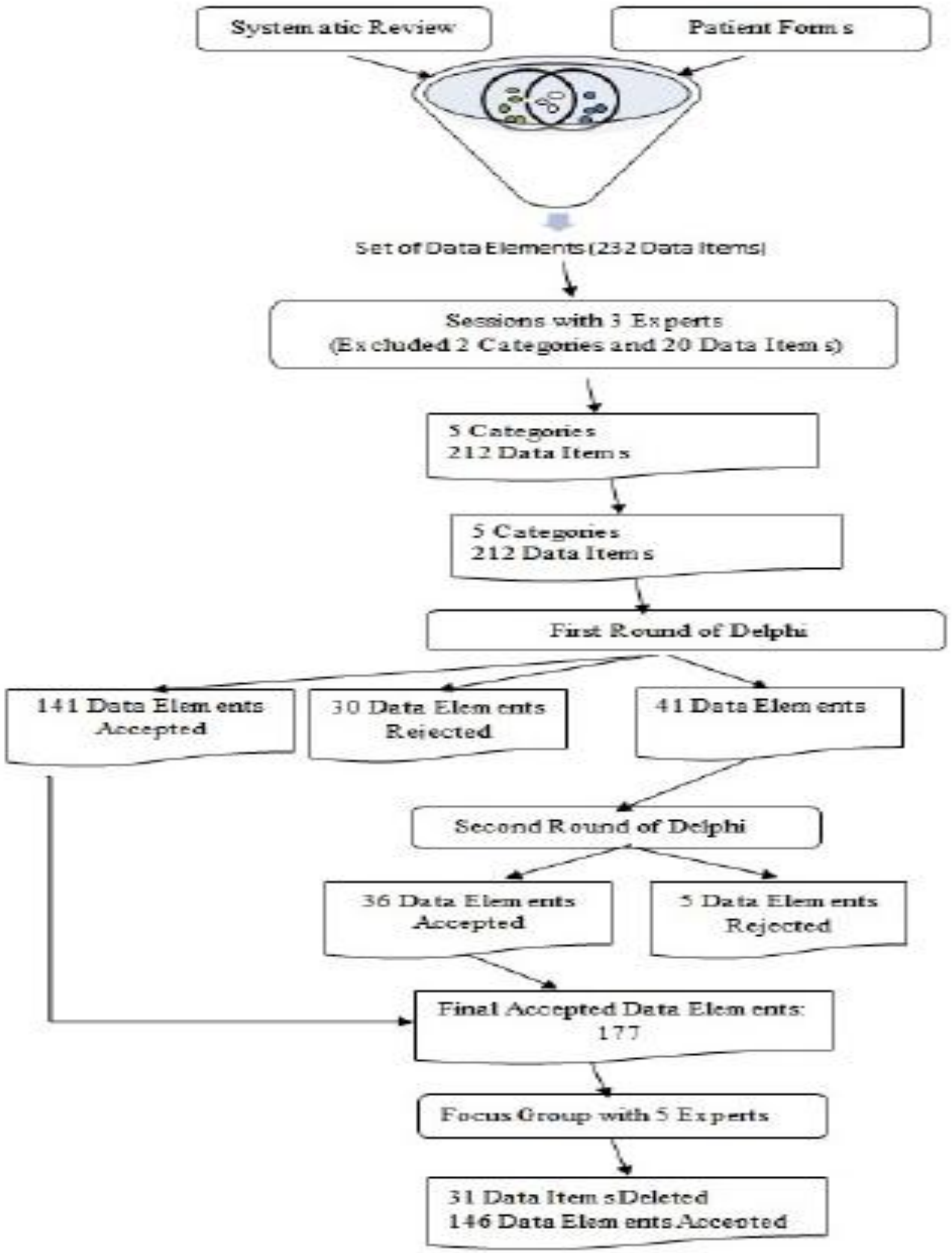
Results

3- Validation of the Data Elements Using the Delphi Technique

- A total of 212 final **data elements** were included in the **Delphi survey**.
- Of these, 141 **data elements** were approved in the **first round**, and **30** were **rejected**.
- A total of **41** **data elements** progressed to the **second round** of the **Delphi survey**.
- Of these, **36** were approved in **round 2**. Thus, on completion of the survey, **177 data elements** were **approved**.

Figure 2

Data Validation Flowchart



Systematic Review

Patient Forms

Set of Data Elements (232 Data Items)

Sessions with 3 Experts
(Excluded 2 Categories and 20 Data Items)

5 Categories
212 Data Items

5 Categories
212 Data Items

First Round of Delphi

141 Data Elements Accepted

30 Data Elements Rejected

41 Data Elements

Second Round of Delphi

36 Data Elements Accepted

5 Data Elements Rejected

Final Accepted Data Elements: 177

Focus Group with 5 Experts

31 Data Items Deleted
146 Data Elements Accepted

Results

4- Determination of the Accessibility of Data Elements Using Focus Group Discussion

- In the **focus group** discussion, **31 data elements** were **removed** by the experts to **ensure accessibility of the data set**.
- The **final minimum data set** included **146 data elements**.

Discussion

- According to the results of the study, **146 data elements** were identified and subsequently categorized into the **General Information**, **Patient History**, **Paraclinical Reports**, **Treatment Plan** (IVF/ICSI, IUI, IO), and **Treatment Outcome** classifications as a **minimum data set** for the purpose of establishing an **infertility registry in Iran**.
- A **minimum data set** that was created in a **developed country** would not apply to a **developing one**.
- The **minimum data set developed** in the current study provides a mechanism by which **information** can be **standardized** and **exchanged** **between** **infertility registries**.

Discussion

- To ensure the inclusion of all relevant data elements, a **systematic review** was conducted before the **experts** were consulted to gauge their opinion. Hence, the **new data elements** were **not** suggested by the **experts** during **round 1** of the **Delphi**.
- In total, **68 percent** of the **experts** from **three private and academic infertility institutions** participated in the **first round of the Delphi technique**.
- It was assumed that the **experts** agreed to participate because they recognize the **need for data recording systems**, the **standardization of patient care forms**, **better treatment follow-up**, and **access to reliable data for research purposes**.

Discussion

- The **minimum data set developed** in the current study included:

- Demographic characteristics of the patients
- Medical history
- Laboratory test results
- Diagnosis
- treatment.

Discussion

- The extent to which the **data elements** complied with the **accessibility criteria** were evaluated during the **focus group** discussions.
- One of the characteristics of **data quality** was the **accessibility of data**. This means that **data elements** should be **easily acquirable** and can be **legally collected** [49, 50].
- According to the World Health Organization, **accessibility** plays a significant role in the **development of healthcare services** [51].

Discussion

- In the current study, **three different methods** were used to develop the **minimum data set**:

- Individual sessions with experts
- A Delphi technique
- A focus group discussion

Discussion

- **Experts** from **three different infertility centers** participated in the study, and **coordination** between them was **difficult**. Hence, it was **not** possible to hold **several focus group** discussions.
- The **Delphi technique** facilitated the process by which information was **shared** among **specialists** from **different geographical areas**.
- Therefore, we used **this technique** to determine which **elements** would be included in the **minimum data set**.

Discussion

- We then needed to **assess** the extent to which the **minimum data set** was **accessible**.
- To decide which **data elements** should be **collected by all infertility centers**, **experts** from all **three infertility centers** discussed and finalized the data set during a **focus group** discussion.

Discussion

limitations

- **First,** the **opinions** and **evaluations** that were employed to finalize the **data set** were derived from **experts** from **only one city**. This city is the second most populated city in Iran. Nevertheless, the minimum data set developed in the current study could be updated by specialists in other cities to develop infertility registries therein.

- **Second,** the **infertility registries** employ **different terms** to describe aspects of infertility. Therefore, after we initially **searched** for and **reviewed** related **keywords**, the **search strategy was modified**, and **new keywords** were added. This process led to the inclusion of **registries** and a **minimum data set** for the **different infertility treatments** in the **second search**.

- **Third, Therapeutic protocols** and **effective parameters** for **diagnosis** and **treatment** may be **changed**. Thus, the **minimum data set** developed for **infertility** in the current study should be **updated in the future**.

Conclusion

- Developing an **infertility registry** using this **minimum data set** could help to generate **higher-quality data** that would lead to **better clinical decisions**.

Thanks for Your Attention

Health Information Technology Department
Mashhad University of Medical Sciences

Lecturer Name: Alireza Banaye Yazdipour

Email Address: yazdipoura961@mums.ac.ir