Studying the seasonal IVF Laboratory Performance Indicators According to the Vienna Consensus 2017 for the High Institute for Infertility Diagnosis and Assisted Reproductive Technologies/Al-Nahrain University, Iraq

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Abstract

Background: Infertility is a medical and financial ailment that affects millions of people worldwide and can lead to stress and psychological distress. It is characterized as the inability to become pregnant clinically after at least a year of regular, unprotected sexual interaction .
Aim : The minimum expected, or competency, values are the values that every laboratory should be able to attain; compare the KPI with these values as well as benchmark values. While aspirational or benchmark values are those that can be used as a baseline for optimal practices (Vienna consensus 2017) .
Patients and methods. The study covered a wide range of patients who had ICSI at the Higher Institute for Infertility Diagnostics and Assisted Reproductive Techniques. Data was gathered from the historical archives of the IVF laboratory dating back to its foundation in addition to establishing KPIs based on the Vienna Consensus (the table below is from the Vienna Consensus, 2017).
Results: we have tow type of results we have Competency valuethe difference was significant. Regarding Benchmark value, also have significant results in each KPI. and have out come pregnancy rate according to season Highest pregnancy rate was seen in winter (39.3 %) followed by autumn (32.6 %) then by spring (22.9 %) and lastly by summer (23.0 %) and the variation in pregnancy rate according to season was significant (p = 0.002) .
Keywords :KPI; ICSI; Pregnancy rate; Vienna Consensus

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intracytoplasmic sperm injection (ICSI),ICSI, or intracytoplasmic sperm
injection, is the process of inserting one live sperm directly into the center of a human egg. The technique was created to help couples whose previous in vitro fertilization (IVF) attempts had failed or who were suffering from severe male factor infertility become pregnant. Couples with low chances of conception can use the procedure to produce viable embryos by reducing a number of obstacles to fertilization. A large number of mature eggs must be released from the female partner's ovaries by stimulation with fertility medicines in order to finish the procedure. The eggs are then delicately aspirated through the vaginal canal using vaginal ultrasonography and kept in an embryology lab. Centrifugation, which includes spinning sperm cells in a specific medium, is used to prepare the sperm sample. Most of the living and dead sperm may then be differentiated from detritus in this manner.The last sperm is then inserted into the egg using a glass needle by the embryologist. In February 1995, the first year ICSI was used at UCSF, we had our first successful ICSI-assisted birth. At UCSF, this method was used to achieve a pregnancy and give birth for the first time in the San Francisco Bay Area. (2002) Damani et al.

***To perform the ICSI process in the laboratory, there are Performance Indicators developed by the international organization ESHRE.**

Performance indicators (PIs) are an essential component of the quality management system (QMS) because they make it possible to assess the efficiency, effectiveness, equity, and patient-centeredness of care (ESHRE Guideline Group on Good Practice in IVF Labs et al, 2016; Mortimer and Mortimer, 2015). There are currently no performance indicators (PIs) and little published data on laboratories using assisted reproductive technology (ART) (Kohn et al., 2000).The goals of this international workshop were to come to an agreement on key performance indicators (KPIs) for oocyte and embryo cryopreservation using slow freezing or

Introduction

Infertility is the clinically confirmed inability to conceive following at least a year of uninterrupted, unprotected intercourse. According to Altamimi et al. (2019), between 8 and 12 percent of couples who are of reproductive age would be affected. Infertility is defined by demographers as the failure of a sexually active, non-contraceptive woman to give birth to a live child (Carrell et.,al 2008).The previous definition of infertility for women over 35 was the failure to get pregnant after at least six months or a year of unrestrained sexual activity. The American Society for Reproductive Medicine, however, recently modified their definition of infertility to include the failure to successfully carry a pregnancy after unprotected sexual contact for a period of 12 months or longer for women ages 20 to 34, or 6 months or longer for women ages 35 and older.(Gurunathetal., 2011).

Assisted reproductive technology (ART) : Infertility can be treated with assisted reproductive technology (ART) (ART). It describes both the male sperm and the female ovum in reproductive operations. It operates by taking a woman's eggs out. Eggs and sperm are combined to create embryos. Then the woman's body receives the embryos back. The most popular and effective kind of ART is in vitro fertilization (IVF)Donor eggs, sperm, or frozen embryos may occasionally be used during ART operations. Additionally, a gestational carrier or surrogate may be involved. A surrogate is a woman who conceives a child in the couple's place using the male partner's sperm. The union of the sperm and eggs from the male and female partners results in pregnancy in the gestational carrier. (Pirtea et.al., 2010) and (Sunderam et., 2015) (Mneimnhet.,al 2013).

Types of ART :

Different techniques and reproductive cells are used in different types of ART operations. Depending on the circumstance, a doctor can suggest the best form of ART. In vitro fertilization is the most typical method of conception (Talaulikaret.,al 2013).One of the best treatments for infertility is

geographic backgrounds.Similar seasonal effects may have an impact on treatment outcomes after ART, according to a popular theory. Researchers have conducted a variety of research to assess the impacts of seasonal variation on ART; nevertheless, the majority of the studies present inconsistent findings. While some studies found that ART conception rates were much higher in the spring and that ART pregnancy rates were higher after ART in the spring, others found that ART conception rates were significantly worse in the autumn.Additionally, other researchers claimed that there was no discernible seasonal variation in LBRs after ART, clinical pregnancy, or fertilization. The variability of the study population, ART methods, ethnicity, and regional variations in the kinds and lengths of seasons may be to blame for the inconsistent outcomes.A study from China is included in the majority of studies, which are mostly focused on populations in Europe and the Middle East. The implications of seasonal fluctuations on the results of ART in South Asia have not been studied in published publications. Studies from Asia and Australia are necessary because of the stark differences in seasonal experiences across different nations.**(**Singhet al,.2021)

Patients and methods

The study comprised a wide range of individuals who went to the consultation clinic before being recommended for an ICSI procedure at the High Institute for Infertility Diagnostics and Assisted Reproductive Techniques**.**The embryologist is in charge of maintaining the books' notes in a tidy and orderly fashion. Data gathering from the IVF laboratories was done on paper and on hard copies. These notebooks are maintained free from any harm sources that could occur, including fire, water, and electrical sources. Although it is not sufficiently ordered to guarantee locating everything, the data collected from the archive room is also stored on paper. Data was collected to compare with the KPI of the international organization ESHRE.

vitrification, minimum performance level values for each KPI, representing fundamental competency, and aspirational benchmark values for each KPI, representing best practice goals. This study gives overviews of current practice and significant criteria in order to develop KPIs. There are benchmarks available for all 14 KPIs. No recommendations were made regarding particular cryopreservation methods or equipment, or if vitrification is "better" than slow freezing, or vice versa, at any given sTo be subjected to quality control (QC) inspection, in vitro fertilization (IVF) laboratories must demonstrate their unaffected or affected performance using a full set of performance indicators. At the Vienna Consensus Meeting in 2017, 12 key performance indicators (KPIs) were presented to summarize a number of essential steps and the overall effectiveness of IVF labs.tage or application (wang et al., 2021).

***KPIs IN THE ART LABORATORY**

The ART procedure is most important in the laboratory because of the work that is done there with gametes and embryos. Above all, it is important to consider these methods and the surrounding area (Hammond et al., 2019).

There are seasonal performance indicators important in ART laboratory Seasonal fluctuations may have a distinct impact on natural conception and birth rates in various populations, according to earlier studies. These modifications follow the effects of climatic, dietary, and social variations on the reproductive physiology of men and women. Longer exposure to daylight may cause decreased melatonin secretion, which has been linked to altered endometrial function in females, a lengthened menstrual cycle, and decreased gonadotrophin secretion.Higher average temperatures have been linked to lower sperm concentration and lower-quality sperm. The frequency of sexual activity and pregnancy rates are also found to be affected by sociocultural differences and seasonal vacations. In addition, the frequency of ovulation and the menstrual cycle may be impacted by the couples' varied eating choices as a result of their varied cultural and

antibodies with two pro nuclei, the quantity of eggs used, the number of embryos created, the timing of their return, and the quality of the sperm antibodies; an embryologist (2PN). There is proof of this in the IVF documents.,Then, we went to the archive section, where we found hundreds of files containing the names of the husband and wife, their ages, their hobbies, their occupations, and the addresses of their homes. Is there a medical or surgical background.The investigation stayed for several months and
collected data..The researchTo collect all the data, collaborate between the IVF
operating room and the archives. information was gathered for the years 2015, 2016, 2017, 2018, 2019, 2020, and 2021. The data comprised 699 or so examples. was unable to discover specific names or files due to the possibility that they had been moved from the operation room to the archive room in order to display the medical reports.

Results

Comparison of ICSI damage rate (IDR) according to season

is shown in table 4.10. Regarding Competency value, the rate of ≤ 10 % was ranging from 77.0 % to 90.4 %, and the difference was significant (p = 0.002). Regarding Benchmark value, the rate of ≤ 5 % was ranging from 76.4 % to 89.1 %, and the difference was significant (p = 0.005)

A form with information was provided at the beginning of the study, and fill it out as instructed. On this form, the husband's name, height, weight, blood type, absence day, volume of semen, concentration, motility, agglutination, and round cell are all listed along with the husband's address, education, occupation, whether or not he smokes, what kind of smoking he does, and any illnesses he may have. What past medical conditions, such as diabetes or high blood pressure, did he have? What past surgeries, if any, did he have? Additional
information discovered includes the wife's name, weight, blood type, age, and hormone analyses for FSH, LH, prolactin, AMH (Anti Mullerian hormone), among other hormones.

Furthermore, it's crucial to know information about embryos, including the number of embryos implanted daily, the number of pro nuclei or embryos injected, the number of follicles, oocytes, or ruptured oocytes, germinal vesicles, MI, or MIII, the date of retrieval, when those transferred, and the grades of embryos.The names of the husband and wife as well as the file number, which contains the majority of the data in the IVF operation records, were obtained from this form and study conducted in the IVF operation room. In addition to the precise date,names, phone numbers, and file numbers are included. Which percentages of people are lost and which are saved? Which developmental stage is it in? the amount of

Table 1.1: Comparison of ICSI damage rate (IDR) according to season

Characteristic	Winter		Spring		Summer		Autumn		Total		*p*
IDR (Competency value)	**n= 191**		**n= 96**		**n= 178**		**n= 229**		**n= 694**		
≤ 10 %	166	86.9	81	84.4	137	77.0	207	90.4	591	85.2	0.002 C **
>10 %	25	13.1	15	15.6	41	23.0	22	9.6	103	14.8	
IDR (Benchmark value)	**n= 191**		**n= 96**		**n= 178**		**n= 229**		**n= 694**		***p***
≤ 5 %	164	85.9	78	81.3	136	76.4	204	89.1	582	83.9	0.005 C **
>5 %	27	14.1	18	18.8	42	23.6	25	10.9	112	16.1	

Comparison of ICSI normal fertilization rate (INFR) according to season

is shown in table 4.10. Regarding Competency value, the rate of ≥ 65 % was ranging from 70.9 % to 76.2 %, but the difference was not significant (p = 0.441). Regarding Benchmark value, the rate of ≥ 80 % was ranging from 54.4 % to 65.1 %, but the difference was not significant (p = 0.441).

Table 1.2: Comparison of ICSI normal fertilization rate (INFR) according to season

Characteristic	Winter		Spring		Summer		Autumn		Total		*p*
INFRC (Competency value)	**n = 172**		**n = 79**		**n = 164**		**n = 208**		**n = 623**		
≥ 65 %	131	76.2	56	70.9	113	68.9	155	74.5	455	73.0	0.441 C NS
<65 %	41	23.8	23	29.1	51	31.1	53	25.5	168	27.0	
INFRB (Benchmark value)	**n = 172**		**n = 79**		**n = 164**		**n = 208**		**n = 623**		***p***
≥ 80 %	112	65.1	43	54.4	99	60.4	128	61.5	382	61.3	0.441 C NS
<80 %	60	34.9	36	45.6	65	39.6	80	38.5	241	38.7	

Comparison of cleavage rate (CR) according to season is shown in. Regarding Competency value, the rate of ≥ 95 % was ranging from 17.1 % to 29.2 %, and the difference was significant (p = 0.021). Regarding Benchmark value, the rate of ≥ 99 % was ranging from 17.1 % to 29.2 %, and the difference was significant (p = 0.021) .

Table 1.3: Comparison cleavage rate (CR) according to season

Characteristic	Winter		Spring		Summer		Autumn		Total		*p*
CRC (Competency value)	**n = 170**		**n = 82**		**n = 153**		**n = 212**		**n = 617**		
≥ 95 %	30	17.6	14	17.1	31	20.3	62	29.2	137	22.2	0.021 C *
<95 %	140	82.4	68	82.9	122	79.7	150	70.8	480	77.8	
CRB (Benchmark value)	**n = 170**		**n = 82**		**n = 153**		**n = 212**		**n = 617**		***p***
≥ 99 %	30	17.6	14	17.1	31	20.3	62	29.2	137	22.2	0.021 C *
<99 %	140	82.4	68	82.9	122	79.7	150	70.8	480	77.8	

Comparison of day 2 embryo development rate (D3EDR) according to season

is shown in table 4.13. Regarding Competency value, the rate of ≥ 50 % was ranging from 72.0 % to 82.5 %, but the difference was not significant (p = 0.504). Regarding Benchmark value, the rate of ≥ 80 % was ranging from 37.5 % to 56.0 %, but the difference was not significant (p = 0.150).

Table 1.4: Comparison of day 2 embryo development rate (D2EDR) according to season

Characteristic	Winter		Spring		Summer		Autumn		Total		*p*
D2EDC (Competency value)	**n = 96**		**n = 35**		**n = 50**		**n = 103**		**n = 284**		
≥ 50 %	77	80.2	28	80.0	36	72.0	85	82.5	226	79.6	0.504 C NS
<50 %	19	19.8	7	20.0	14	28.0	18	17.5	58	20.4	
D2EDRB (Benchmark value)	**n = 96**		**n = 35**		**n = 50**		**n = 103**		**n = 284**		***p***
≥ 80 %	36	37.5	16	45.7	28	56.0	51	49.5	131	46.1	0.150 C NS
<80 %	60	62.5	19	54.3	22	44.0	52	50.5	153	53.9	

Comparison of day 3 embryo development rate (D3EDR) according to season

is shown in table 4.14. Regarding Competency value, the rate of ≥ 45 % was ranging from 65.8 % to 81.8 %, but the difference was not significant (p = 0.154). Regarding Benchmark value, the rate of ≥ 70 % was ranging from 43.5 % to 69.3 %, and the difference was significant (p = 0.006).

Table 1.5: Comparison of day 3 embryo development rate (D3EDR) according to season

Characteristic	Winter		Spring		Summer		Autumn		Total		*p*
D3EDRC (Competency value)	**n = 59**		**n = 38**		**n = 88**		**n = 92**		**n = 277**		
≥ 45 %	45	76.3	25	65.8	72	81.8	64	69.6	206	74.4	0.154 C NS
<45 %	14	23.7	13	34.2	16	18.2	28	30.4	71	25.6	
D3EDRB (Benchmark value)	**n = 59**		**n = 38**		**n = 88**		**n = 92**		**n = 277**		***p***
≥ 70 %	30	50.8	21	55.3	61	69.3	40	43.5	152	54.9	0.006 C *
<70 %	29	49.2	17	44.7	27	30.7	52	56.5	125	45.1	

Comparison of Blastocyst development rate (BDR) according to season

shown in table 4.15. Regarding Competency value, the rate of ≥ 40 % was ranging from 55.6 % to 76.5 %, but the difference was not significant (p = 0.584). Regarding Benchmark value, the rate of ≥ 60 % was ranging from 44.4 % to 62.5 %, but the difference was not significant (p = 0.850)..

Table 1.6: Comparison of Blastocyst development rate (BDR) according to season

Characteristic	Winter		Spring		Summer		Autumn		Total		*p*
BDRC (Competency value)	**n = 9**		**n = 7**		**n = 17**		**n = 16**		**n = 49**		
≥ 40 %	5	55.6	4	57.1	13	76.5	12	75.0	34	69.4	0.584 C NS
<40 %	4	44.4	3	42.9	4	23.5	4	25.0	15	30.6	
BDRB (Benchmark value)	**n = 9**		**n = 7**		**n = 17**		**n = 16**		**n = 49**		***p***
≥ 60 %	4	44.4	4	57.1	10	58.8	10	62.5	28	57.1	0.850 C NS
<60 %	5	55.6	3	42.9	7	41.2	6	37.5	21	42.9	

Comparison of Blastocyst cryosurvival rate (BCSR) according to season

is shown in table 4.16. Regarding Competency value, the rate of ≥ 90 % was ranging from 68.8 % to 100 %, but the difference was not significant (p = 0.300). Regarding Benchmark value, the rate of ≥ 99 % was ranging from 62.5 % to 100 %, but the difference was not significant (p = 0.156).

Table 1.7: Comparison of Blastocyst cryosurvival rate (BCSR) according to season

Characteristic	Winter		Spring		Summer		Autumn		Total		*p*
BCSRC (Competency value)	**n = 9**		**n = 7**		**n = 17**		**n = 16**		**n = 49**		
≥ 90 %	8	88.9	7	100.0	14	82.4	11	68.8	40	81.6	0.300 C NS
<90 %	1	11.1	0	0.0	3	17.6	5	31.3	9	18.4	
BCSRB (Benchmark value)	**n = 9**		**n = 7**		**n = 17**		**n = 16**		**n = 49**		***p***
≥ 99 %	8	88.9	7	100.0	14	82.4	10	62.5	39	79.6	0.156 C NS
<99 %	1	11.1	0	0.0	3	17.6	6	37.5	10	20.4	

Ongoing pregnancy rate according to season

is shown in table 4.18. Highest pregnancy rate was seen in winter (39.3 %) followed by autumn (32.6 %) then by spring (22.9 %) and lastly by summer (23.0 %) and the variation in pregnancy rate according to season was significant (p = 0.002) .

Table 1.8: Ongoing pregnancy rate according to year

Season	Total	Positive	Negative	*p*
Winter	191	75 (39.3 %)	116 (60.7 %)	0.002 C **
Spring	96	22 (22.9 %)	74 (77.1 %)	
Summer	178	41 (23.0 %)	137 (77.0 %)	
Autumn	230	75 (32.6 %)	155 (67.4 %)	

Competency value, the rate of ≥ 50 % was ranging from 72.0 % to 82.5 %, but the difference was not significant (p = 0.504). Regarding Benchmark value, the rate of ≥ 80 % was ranging from 37.5 % to 56.0 %, but the difference was not significant (p = 0.150). Its good results. Comparison of day 3 embryo development rate (D3EDR) according to season is shown in table 4.14. Regarding Competency value, the rate of ≥ 45 % was ranging from 65.8 % to 81.8 %, but the difference was not significant (p = 0.154). Regarding Benchmark value, the rate of ≥ 70 % was ranging from 43.5 % to 69.3 %, and the difference was significant (p = 0.006).Agreed with (Kutlu, Pet.,al 2021)Comparison of Blastocyst development rate (BDR) according to season is shown in table 4.15. Regarding Competency value, the rate of ≥ 40 % was ranging from 55.6 % to 76.5 %, but the difference was not significant (p = 0.584). Regarding Benchmark value, the rate of ≥ 60 % was ranging from 44.4 % to 62.5 %, but the difference was not significant (p = 0.850).The results agreed with (Kutlu, P et.,al 2021). Comparison of Blastocyst cryosurvival rate (BCSR) according to season is shown in table 4.16. Regarding Competency value, the rate of ≥ 90 % was ranging from 68.8 % to 100 %, but the difference was not significant (p = 0.300). Regarding Benchmark value, the rate of ≥ 99 % was ranging from 62.5 % to 100 %, but the difference was not significant (p = 0.156**)** .Probably reason are: Type of cryopreservation media , Fluctuating temperature.Ongoing pregnancy rate

Discussion

Comparison of ICSI damage rate according to season is shown in table 4.10. Regarding Competency value, the rate of ≤ 10 % was ranging from 77.0 % to 90.4 %, and the difference was significant (p = 0.002). Regarding Benchmark value, the rate of ≤ 5 % was ranging from 76.4 % to 89.1 %, and the difference was significant (p = 0.005) ,The probably reason is : Temperature fluctuationIncubator humidity, Gas flow ,Suboptimal medium culture, Contamination,Intrinsinc embryo problem. Comparison of ICSI normal fertilization rate (INFR) according to season is shown in table 4.10. Regarding Competency value, the rate of ≥ 65 % was ranging from 70.9 % to 76.2 %, but the difference was not significant (p = 0.441). Regarding Benchmark value, the rate of ≥ 80 % was ranging from 54.4 % to 65.1 %, but the difference was not significant (p = 0.441).The increase results fertilization in winter and autumn , agreed with(Korkmaz et al.,2021)and (Weigert et al., 2001).Comparison of cleavage rate (CR) according to season is shown in table 4.12. Regarding Competency value, the rate of ≥ 95 % was ranging from 17.1 % to 29.2 %, and the difference was significant (p = 0.021). Regarding Benchmark value, the rate of ≥ 99 % was ranging from 17.1 % to 29.2 %, and the difference was significant (p = 0.021). Temperature fluctuation,Suboptimal medium culture ,Contamination. Comparison of day 2 embryo development rate (D3EDR) according to season is shown in table 4.13. Regarding

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according to season is shown in table 4.18. Highest pregnancy rate was seen in winter (39.3 %) followed by autumn (32.6 %) then by spring (22.9 %) and lastly by summer (23.0 %) and the variation inwas significant (p = 0.002). (Korkmaz et al.,2021)and (Weigert et al., 2001).

Conclusions:

1.The standard efficiency values that every laboratory should be able to achieve, the lowest expected values, and the efficiency values that can be used as best practice were contrasted in this study. The outcomes are satisfactory and favorable. 1. The standard efficiency values that every laboratory should be able to achieve, the lowest expected values, and the efficiency values that can be used as best practice were contrasted in this study. The outcomes are satisfactory and favorable.

2.The study has produced suggestions that help the performance quality improve and recommendations relating to the laboratory database as documentation.

3.Occasionally, there might not be a formal marriage contract when the file is opened, which could cause us legal problems.

Recommendations:

1.Based on the results of the study, it is advised that electronic documentation be utilized in addition to paper to ensure that data is not lost when it is removed by the patient and that it is preferred to be given.

2 .Recommend that the electronic device be kept both on a special hard drive and an internet storage system. Include all imported data and the details of the cycle to prevent data deletion during computer repair.

3 .Recommend that the patient's age be determined before the ICSI procedure is started to avoid affecting the pregnancy's result.

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