

BILLING VARIANCE OF EMBRYO INVENTORY DURING IVF

Dissertation Submitted to



The IIHMR University, Jaipur

for the partial fulfillment for the award of the degree of

Master of Business Administration (MBA)

in

Hospital and Health Management

by

Ayan Lahiri

Under the Supervision and Guidance of

Dr. S. D Gupta

2021

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TO WHOMSOEVER IT CONCERNS

DECLARATION BY STUDENT

I hereby declare that this dissertation titled **Billing variance of embryo inventory during IVF** is the bonafide record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.

Ayan Lahiri
29.06.2021

CERTIFICATE



28-June-2021

TO WHOMSOEVER IT MAY CONCERN

This is to certify that Ayan Lahiri in partial fulfillment of the requirements for the award of the degree of MBA (Hospital and Health Management) from the IIHMR University, Jaipur has successfully completed his internship (dissertation project) at Nova Pulse IVF Clinic Private Limited during 05th April, 2021 to 18th June, 2021.

For Nova Pulse IVF Clinic Private Limited

A handwritten signature in blue ink, appearing to read "Rupali", written over a horizontal line.

Rupali C Rane
Head – Human Resources

Nova Pulse IVF Clinic Private Limited

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CIN number: U74900KA2010PTC055474

CERTIFICATE

This is to certify that dissertation title **Billing variance of embryo inventory during IVF** is a record of the research work undertaken by Ayan Lahiri in partial fulfillment of the requirements for the award of the degree of MBA (Hospital and Health Management from the IIHMR University, Jaipur under my guidance and supervision and his/her approach to the research study has been sincere, scientific, and analytical.

Faculty Guide:
Dr. S. D Gupta
IIHMR University, Jaipur
Date: 29.06.2021

School Dean:
Dr. Dhirendra Kumar
IIHMR University, Jaipur

ABSTRACT

Introduction

IVF is a very serious clinical procedure, which helps the patients to conceive. In this particular process the oocytes are extracted from the female ovaries and then process of fertilization is carried out in the lab. There are many factors associated with the delivery of healthy baby using the IVF such as the patients age etc. Due to change in the current lifestyle, acquired by the people is leading to an increased incidence of NCD's. The rising incidence of NCD's and other factors associated with it has resulted into infertility. Infertility can also be observed with increasing age, so nowadays the patients who want to have a child after a certain period, gets their oocytes extracted and cryopreserved. Cryopreservation comes with a subscription model. This subscription needs to be chosen after the OPU extraction.

The billing variance in the fertility business causes when the payment gets stuck, and the proposed amount does not float in the balance sheet of the business entity. Billing variance is the gap between the projected payor value and the payment made to the business.

Objective

The objectives of the study are-

- To assess the IVF industry.
- To assess the variations in embryo renewal billing based on the primary data available.
- To assess the factors impacting the billing variance against the embryo storage.

Methodology

A descriptive research was conducted using the various existing literature and data from an IVF clinic EHR to find out the research outcomes. IVF process assessment regarding the cryopreservation was carried out. Parameters like OPU, vitrification, embryo renewal packages, follow up pattern was considered in this study.

Key Results

The factors that are driving the billing variance in the embryo storage in the fertility clinics are the higher cost of the fertility treatments, non-compliance of patients in the treatment process as this process is very economically, emotionally, and physically

strenuous. There are multiple operational errors which are also driving the billing variance in the IVF business.

Key words: IVF, OPU, Vittrification, EHR, Cryopreservation

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IIHMR University, Jaipur

Date: 29.06.2021

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ABBREVIATIONS

IVF	“In-vitro fertilization”
HCG	“Human Chorionic Gonadotropin”
OPU	“Ovum pick up”
FSH	“Follicle Stimulating Hormone”
LH	“Leutinizing Hormone”
ET	“Embryo Transfer”
ICSI	“Intracytoplasmic sperm Injection”
EHR	“Electronic Health Record”
IRDAI	“Insurance Regulatory and Development Authority”
ICMR	“Indian Council of Medical Research”
HMIS	“Health Management Information System”

Billing Variance of embryo inventory during the IVF procedure

1. Introduction

1.1 IVF sector in India:

“In vitro fertilisation (IVF)” defined as a critical set of clinical treatments intended to improve fertility, prevent abnormalities due to genes, an aid in conceiving a child or infant. “In this process mature oocytes are retrieved from the ovaries and fertilized by sperm in a laboratory.” These fertilized embryos are implanted to the uterus. It generally takes 3 weeks to complete a full cycle. In some cases, these means are parted into various segments and the cycle can take more time. The most effective form of the assisted reproductive technology is IVF. These procedures can be done by using eggs of the patients and the sperms of the partner. It also can be done by the involvement of the sperms, eggs, or embryos from a known or anonymous donor.

The chances of having healthy infant using the “In vitro fertilization”, depends upon many circumstances such as the age of the patient, the reason behind infertility etc. The IVF process is time-consuming, invasive, and expensive. It has also been observed that, if more than one embryo is transferred, the chances of conceiving increases, but on the other hand chances of twins and triplets also come into existence.

1.2 IVF Market landscape in India

IVF Market is projected to expand at a rate of 13% and exceed the market value of \$1 billion by FY 2026.

The country’s IVF market is being driven by the increased accessible and affordable health infrastructure.

This aspect is also fuelling the IVF sector by encouraging medical tourism. Furthermore, shifting lifestyle habits are causing disorders such as PCOS.

Furthermore, the growing demand of the single specialty hospitals is projected to fuel the market over the next few years. Growing public awareness of male infertility in the country is projected to have a beneficial impact on the market in the coming years.

In India, there are about 2-2.5 lakh IVF cycles in a year and has the potential to do about 5-6 Lakh IVF cycles. With the increasing population and increasing infertility

rate, healthcare professionals must make IVF procedures accessible and affordable along with raising awareness.

1.3 Why In vitro fertilization?

IVF is mostly offered to those patients who suffer from infertility in women aged above 35. It can be also done if the patient suffers from different health condition.

IVF, is also an option when any of the partner has certain below mentioned health condition:

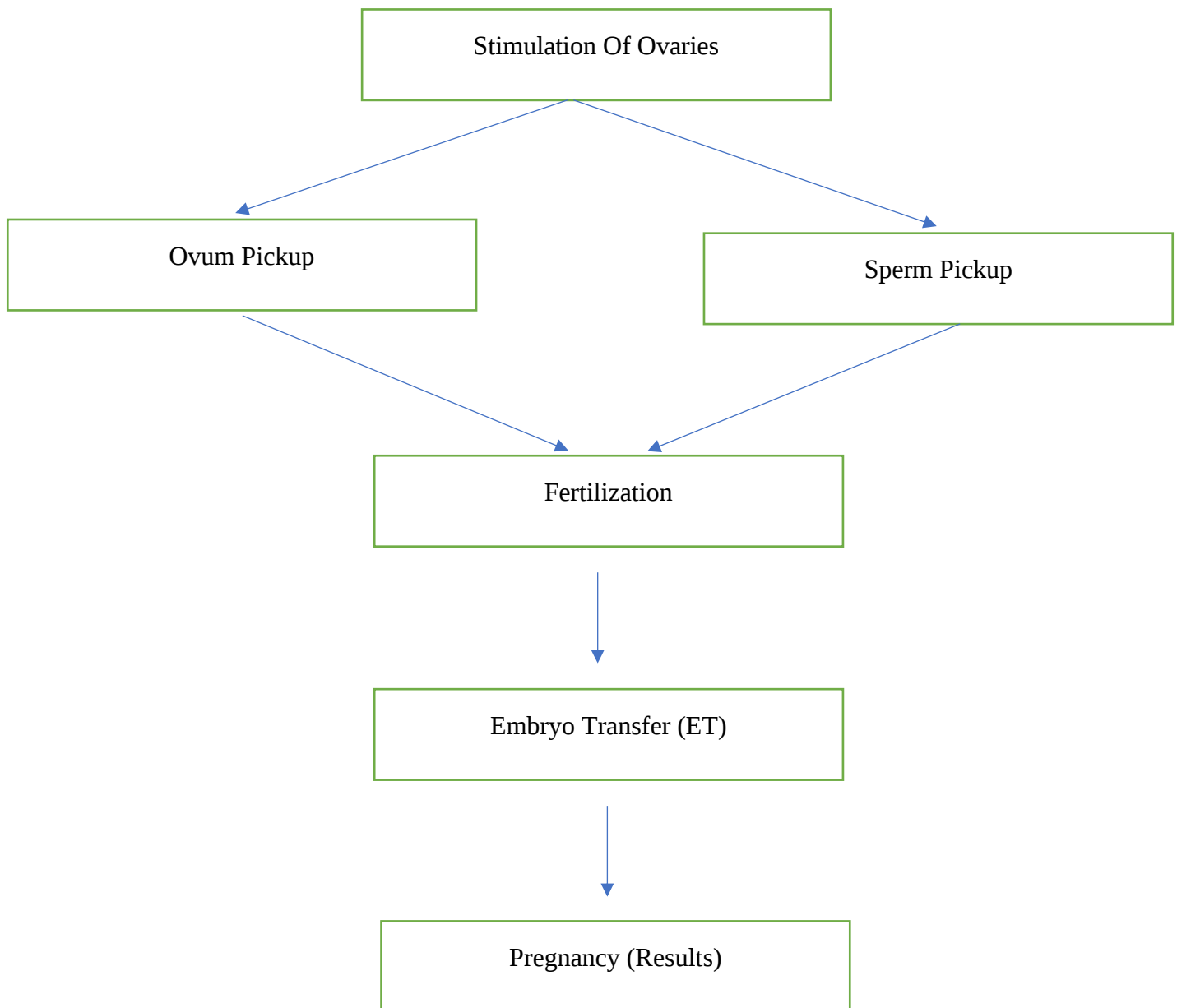
- Fallopian tube blockage/damage: it makes the egg difficult to fertilize or make a way for the embryo to travel to the uterus.
- Uterine fibroids: These are a kind of tumours, present in the uterus wall which are commonly found in the women in their's 30's and 40's.
- Damaged sperm production: Poor quality and abnormalities of sperm such as in shape and size can be very difficult for the sperm to fertilize egg.
- Endometriosis: It occurs when the uterine tissue implants start growing outside the uterus. It mostly affects the functioning of the ovaries, fallopian tubes, and the uterus.
- Ovulation Problem or disorder: When the ovulation is less or totally absent, there are only few eggs for the fertilization process.
- Fertility preservation: This is often done for those patients who undergo different health procedures, which involves using different drugs and procedures for treatment. For example: If a patient is about to start Cancer treatment, this treatment comprises of using clinical techniques such as chemotherapy and radiation, these treatments could harm the fertility of the patients. To avoid these circumstances, patients can use IVF for cryopreservation as an option. Where females can retrieve the oocytes from their ovaries and can freeze those eggs in fertilized and unfertilized condition, so that can be used in future when the treatment is completed.

1.4 Risks associated with In vitro fertilization.

- Multiple Birth: The IVF process increases the change of multiple births, if 1 or more embryos are implanted.

- “Miscarriage: Miscarriage rates for women who conceive through IVF with fresh embryos are similar to those for women who conceive spontaneously, ranging from 15% to 25%, however the rate rises with maternal age.”
- Ovarian Stimulation Syndrome: Use drugs (fertility) through injections like the “human chorionic gonadotropin (HCG)”, to influence ovulation can cause “ovarian stimulation syndrome”, where ovaries swell up and becomes painful.
- Low birth weight and premature delivery: It raises the chances of the baby being born prematurely or with a low birth weight.
- “Ectopic Pregnancy: An ectopic pregnancy occurs when a fertilised egg implants outside the uterus, generally in a fallopian tube, in about 2% to 5% of women who undergo IVF. The fertilised egg will not survive outside the uterus, and the pregnancy will be terminated.”
- Ovum Pickup Complications: This process requires OPU needles which can possibly lead to bleeding, infection or damage to the blood vessels, bowels, or the bladders during the ovum pickup. Several risks are also associated with general anaesthesia and sedation.
- Stress: The process of IVF could be physically, emotionally and economically strenuous. Continuous support from the professionals such as the counsellors and the family members should be given during the IVF treatment.

1.5 In-Vitro fertilization flow process: -



- Stimulation of ovaries: If the patients are using their own eggs during the IVF process, the patient will be given the treatment of synthetic hormones to stimulate the ovaries to produce several eggs. This process is done because some of the eggs won't fertilize or develop after fertilization. Multiple variations of medicines could be used for the process such as the:

- ❖ For stimulation of ovaries: Medications are given because to stimulate more than one egg at a time. To do the process, medications containing “follicle-stimulating hormone (FSH)”, a “luteinizing hormone (LH)” or a combination of both are given as an injection.
- ❖ For oocyte maturation: Likely after 8-14 days, patients are given human chorionic gonadotropin (HCG) or some different medicines for the eggs to get matured.
- ❖ To prevent pre-mature ovulation: these medication helps the patient’s body to hold the developing eggs rather than leaving it too soon.
- ❖ Prepare lining: On the day of egg transfer or retrieval, the patients are recommended by the doctor to take “progesterone supplements” to make the uterus lining, receptive to implantation.
- Ovum Pickup: It is generally carried out in the IVF clinic, after 34-36 hours from the final injection and the ovulation.
 - The patient will be given pain medications or anaesthesia at the time of pickup.
 - The oocytes are extracted from the follicles by the OPU needles attached through a suction machine.
 - Multiple eggs can be removed within 30 minutes.
 - These retrieved eggs are kept in the culture dish along with culture media and are incubated.
- Sperm Pickup: If the patient is using the partners sperm, the partner needs to provide the semen sample at the IVF clinic in the morning of ovum pickup. Then these sperms get segregated from the semen fluids in the andrology lab.
- “Fertilization”: It is carried out in 2 conditions. It solely depends upon the patient’s health condition. These are directed by the clinicians.
Such as:
 - Conventional Insemination: “In this process the healthy quality of sperms and the matured eggs are merged and kept overnight for incubation.”
 - “Intracytoplasmic sperm Injection (ICSI)”: it is often used when the semen quality along with other conditions like fertilization attempts gets failed during the prior IVF cycle. In this process “ICSI”, a healthy single sperm is directly infused in each of the matured eggs.

- Embryo Transfer (ET): Generally, embryo transfer is usually done in the IVF clinics.
 - There might be use of anaesthesia. Mostly it is a painless procedure, mild cramps are observed in few cases.
 - In this process, clinician might use catheter to insert into your vagina.
 - Now, with the help of syringe, clinicians place the “embryo/embryos” into the uterus.
- Pregnancy (Results): Clinicians would request the patient to get their blood tested in between 12-14 days after the egg extraction process to detect pregnancy.
 - Pregnancy Successful: IVF clinician would refer the patient to the obstetrician for the prenatal care.
 - If not pregnant: If the patient is willing to attempt another set of “IVF” cycle, the clinicians would suggest/advice different kinds of steps so that the patient can take steps to improve the chances of conceiving.

1.5 Billing Variance

Billing variance in healthcare is the gap between the projected payor value of a bill and the payments made to the business. Billing variance can have a variety of causes, but they usually fall into one of two groups.

When a payer has upgraded their payment system/package, and they differ to pay as per the new contract price schedule, they fall into the first group.

When a organization makes modifications in their billing system, but the configuration isn't successfully implemented, the second significant category of occurrence that might create payment discrepancies is when the changes aren't effectively applied.

Because both eventualities are more likely to occur at the beginning of a new contractual year, now is the time to examine any payment differences that arise before they spiral out of control.

The goal of any such organizations should be to collect approximately 95-100% of their outstanding payment before or just after their due date from their consumers. The organization needs to identify small errors (monetary valuation) of revenue pilferage due to the non-renewal of the embryos. As the errors with respect to the number of cases are increasing every financial year, it can contribute to huge chunk of money flowing out from the balance sheet.

Hence, this study has explored the possible billing variations in embryo renewal caused during IVF process.

2 Research Question

- ❖ What is billing variance? What are the variations in embryo renewal billing?
- ❖ What are the factors impacting the billing variance associated with embryo inventory?

3 Research Objectives

- To assess the IVF industry.
- To assess the variations in embryo renewal billing based on the primary data available.
- To assess the factors impacting the billing variance against the embryo storage.

4 Review of Literature

Author	Objective	Study Location	Methodology	Salient Features
“Lahav et. al (Data creation) (2020)”	“An optimal pricing policy for human embryo storage services is developed. The suggested model reduces the unused stored embryos.”	Bar-Ilan University, Israel	-	“This study looks at a one-of-a-kind challenge: the storage of frozen embryos after IVF treatments. It is a challenge with economic, ethical, and social implications. The model brings together the needs of a (a) couples who use the storage service in the primary market; (b) couples who want to donate embryos on the secondary market for a variety of reasons; (c) the service provider who wished to maximise profit; and (d) the social planner who wants to reduce the number of unused

				embryos while keeping the option of embryo donation on the secondary market or for research.”
“Konc J, Kanyó K, Kriston R, Somoskyi B, and Cseh B (March, 2014)”	-	“Infertility and IVF Center of Buda, Szent János Hospital, Budapest, Hungary”	-	“Embryo cryopreservation has reduced the number of fresh embryo transfers while increasing the IVF cycle's efficiency. According to the findings, transferring cryopreserved embryos resulted in 8% more births for women who underwent fresh and frozen embryo transfers. When compared to embryo freezing, oocyte cryopreservation offers greater benefits, such as fertility preservation in women who are already at a danger of losing their fertility owing to oncological treatment or chronic disease.”

“Provoost V, Pennings G, Sutter PD, and Dhont M”	“The objective of this study is to describe patients who at least once did not reply to correspondence of the centre about embryo disposition.”	Ghent University, Belgium	Questionnaire based survey	“Patients' response behaviour, personality traits, embryo disposition decision, and opinions concerning this decision. The percentage of those that responded was 79 percent. Nonrepliers made up 12% of the patients, largely because they couldn't make a (shared) decision. Nonrepliers were older, had a longer treatment cycle, and had a higher likelihood of a bad result. Nonrepliers were twice as likely as other patients to be childless. They also expressed more anticipated remorse about the decision, and they placed a higher value on their embryos when used for their own treatment. In both groups, the proportion of patients who rarely thought about their embryos was the same.”
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5 Research Methodology

- Study Design: Observational-Descriptive Study
- Study Location: NOVA IVF Fertility center
- Type of analysis: Mixed Study Type (Qualitative and Quantitative)
- Primary data retrieved from the IVF clinic database was used for the analysis, to find out the embryo renewal billing variances.
- The database sources for the secondary collection of data were extracted from PubMed, Science Direct, Google Scholar, website articles, and blogs were used.
- The data analysis has only been carried out for the FY 2015-2020. The reason being-
 1. The previous year data were not available in the EHR.
 2. As per the industry standard the embryo storage has generally the time frame of 5 years.
 3. Drop-out rate in IVF cycles is quite very high. Because cases above 5 years generally tend to drop-out or have changed their decision regarding IVF or pregnancy.
- Firstly, to understand the real time problem. Secondly, had a close observation of how the IVF lab functions. The process of cryopreservation and the how it is being carried out and observed the assessment of the renewal cases. Data was collected from the clinic's EHR and it was verified. The data presented here were those which were verified in the EHR's database as well as the laboratories. Parameters like total IVF cases carried out against the embryo renewal are compared from a FY. The reasons why the non-renewal are higher and what factors influence the non-renewal of the frozen embryos were studied.

6 Results and Discussion

6.1 Variations in embryo renewal billing: -

6.1.1 Embryo freezing

It is the process by which the embryos are preserved and use them later. The biggest challenge for freezing these embryos is the water present inside the cells, when these water freezes, there might be a formation of crystals, which can burst the cell.

Doctors nowadays use the process called cryopreservation, to prevent this thing to happen. Clinicians use a substance called the cryoprotectant, which replaces the water in the cell. Then these embryos are incubated in the increasing level of cryoprotectant before freezing them. After almost all the water is removed from those embryos, the clinicians cool the embryos to its preservation state.

The embryos are mostly freeze by any of the two ways mentioned below:

- “Slow freezing: This involves placing the embryos in sealed tubes, then slowly lowering their temperature. It prevents the embryo’s cells from aging and reduces the risk of damage. However, slow freezing is time-consuming, and it requires expensive machinery.”¹⁴
- “Vitrification: In this process, the doctor freezes the cryoprotected embryos so quickly that the water molecules do not have time to form ice crystals. This helps protect the embryos and increases their rate of survival during thawing.”¹⁴

After freezing process is completed, the embryos are stored in liquid nitrogen. The embryos are kept in a sealed container at a temperature around -321°F. At this temperature, no biological transformation can happen such as aging.

6.1.2 Embryo Renewal billing process and components used: -

A frozen embryo which are stored with the clinic, can remain viable for a longer period. There are some countries whose medical agencies, who regulates the timeframe for storage of the embryo’s.

Freezing and storing embryos are costly, and each clinic has its own set of restrictions for what happens if a person can no longer use or keep their embryos frozen.

The components which are mostly used in the embryo renewal process are:

- Liquid nitrogen
- Cryotops
- Freezing Media
- Petri-dish

The embryo renewal billing process start just after the stage of blastocyst, where the clinicians segregate the embryos according to the embryo quality. Then if the patients want to conceive immediately, then the embryos are transferred and rest of the embryos can be frozen for the future use, if required.

On the other hand, if some patients are going for some treatment which can make them infertile or want to store their eggs for delayed pregnancy, generally choose to store the embryos.

The embryo billing depends upon the healthcare facility. Generally, after the ovum pickup, the patients are given choice to choose their own storage package.

Here are some packages which are generally used by the IVF facility in India:

- Embryo Freezing – 6 months
- Embryo Freezing – 9 months
- Embryo Freezing – 12 months
- Embryo Freezing – 36 months
- Embryo Freezing – 60 months

“In India, freezing embryo costs Rs. 10,000 to Rs. 15,000 per month.”⁶

These are option's which patients can avail after the completion of the stipulated freezing period:

- The patients need to renew their packages before or just after the due date.
- They might also consider the option of getting the embryos transferred for future childbearing/pregnancies.
- If neither of the above mentioned are un-wanted by the client, the embryos can be discarded with their consent.

Much has been said about the ethical and moral difficulties surrounding how to deal with these extra embryos.

There are four probable outcomes for these embryos in general:

- “Thawing and discarding”,
- “Donating to research”,
- “Indefinite storage”,
- “Donating the embryos to another couple for the purposes of uterine transfer.”

Percentage of embryo billing variations observed during fiscal year
2015-16 to 2019-20 across 6 centers in South India

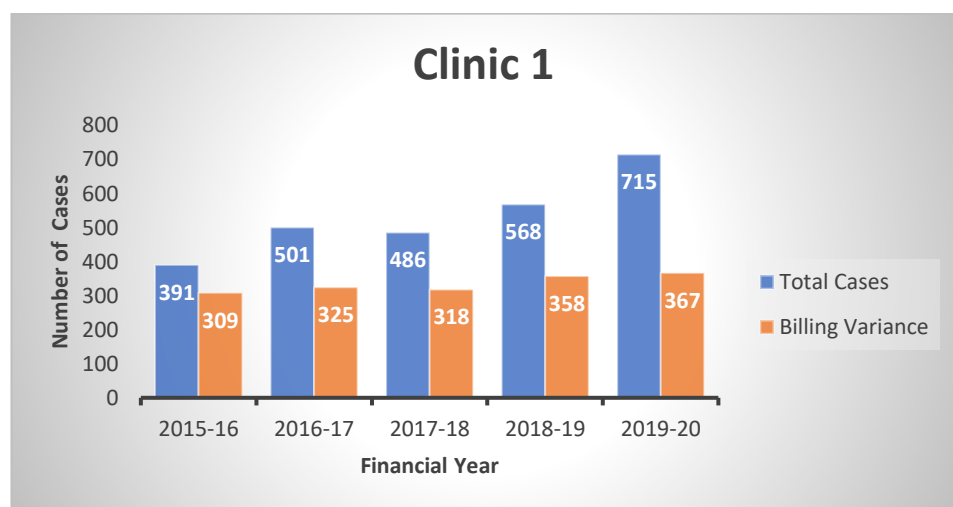


Figure 6.1.1

From this Figure 6.1, it was observed that there was total 2661 cases in the Clinic taken from the FY 2015-16 to 2019-20. It also indicates that 63% billing variation out of the total cases was seen in the clinic.

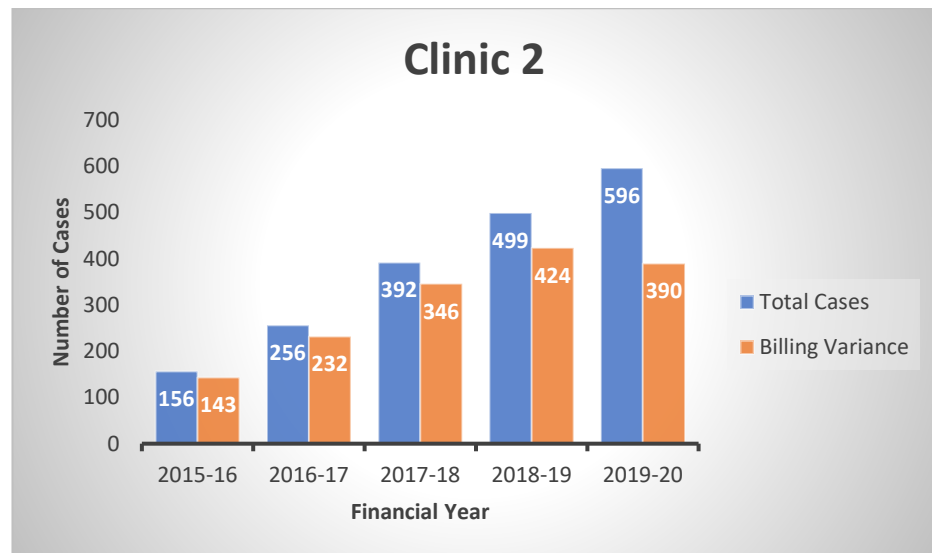


Figure 6.1.2

From the fiscal years 2015-16 to 2019-20, there were a total of 1899 cases in Clinic. It also shows that there was an 81 percent billing variance at the clinic.

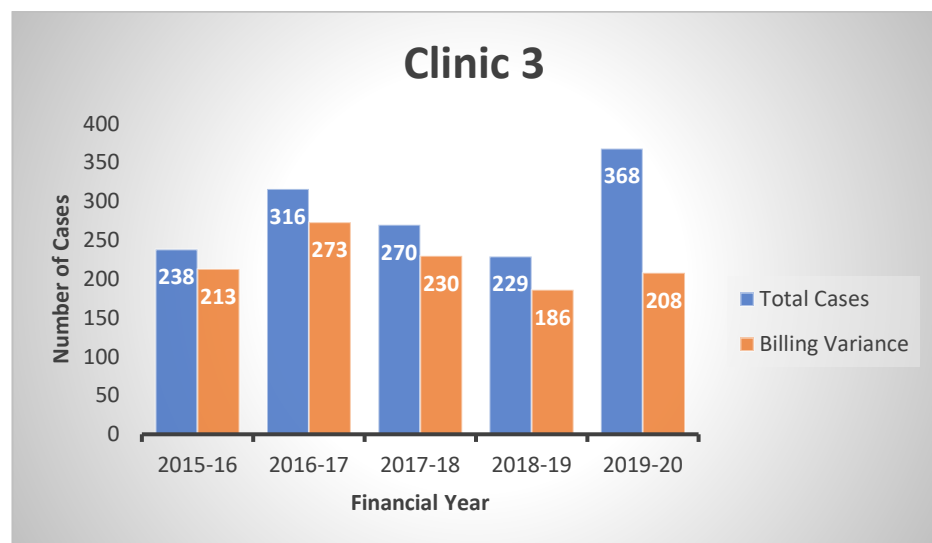


Figure 6.1.3

There were a total of 1421 cases in Clinic between fiscal years 2015-16 to 2019-20. It also indicates that the clinic had an 78 % of billing variance from the total number of cases.

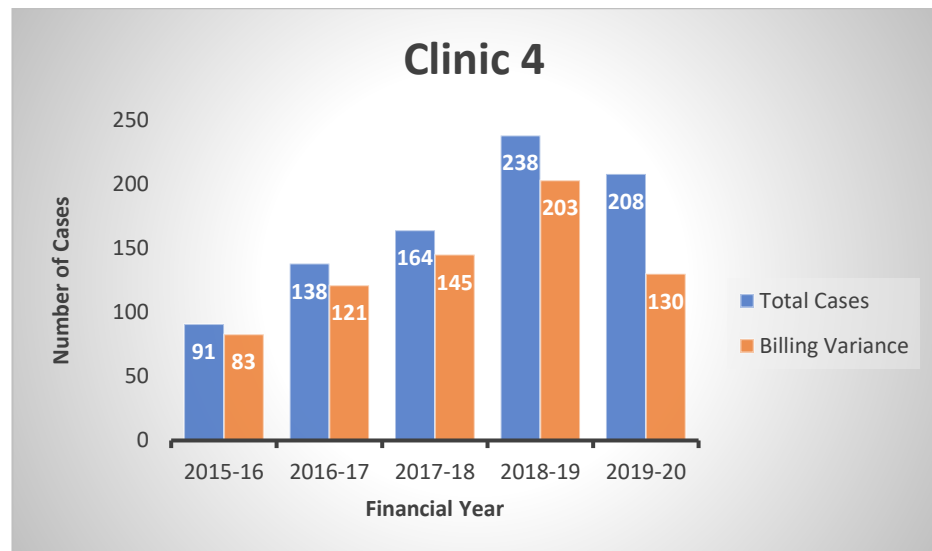


Figure 6.1.4

This clinic had a total case load of 839 cases from the financial year 2015-16 to 2019-20. The billing variance against the embryo storage was found to be 81% of the total caseload.

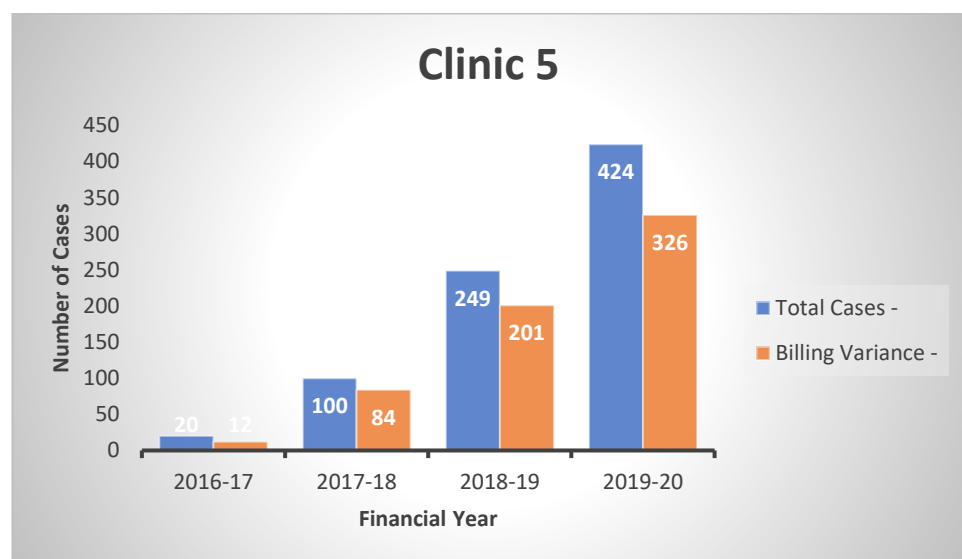


Figure 6.1.5

This clinic was started by the group in the fiscal year 2016-17 and the total caseload registered till 2019-20 was 793. And this clinic also shows a billing variance in between 78-79% of the total caseload.

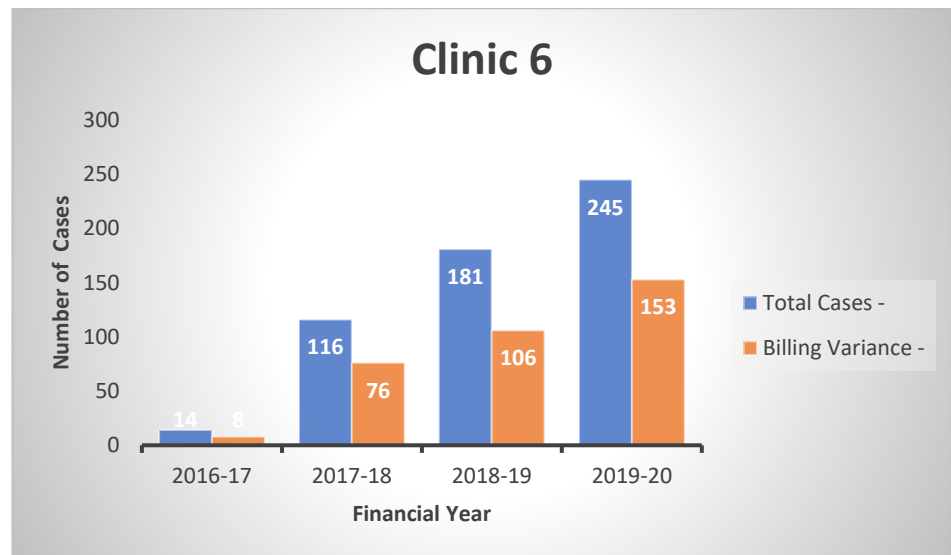


Figure 6.1.6

The group began its clinic in the fiscal year 2016-17, and there were 556 cases registered till 2019-20. In addition, this clinic's billing variation is 62 percent of the entire caseload.

These graphs depict that the billing variation against the embryo renewal in the respective clinics are between 62-82 percent.

The money, which is floated in the market without being recovered, is as huge as 82 percent. This amount has not impacted the business before financial year 2020-21 because the primary element of the IVF business is OPU per patient. With the onset of the pandemic, there was a sudden drop in the patient flow, which made the company to think about the alternate method of generating revenue for keeping the business running.

The embryo renewal is also very important as the expenditure to store the embryos is very less and most of the cost involving process is carried out during the initial stage. Hence, most of the revenue generated from the renewals directly contribute to the bottom-line of the business and hence it directly impacts the balance sheet of the organization.

6.2 Factors impacting billing variance: -

➤ **Non-compliance: -**

- ***According to an article in the European Society of Hypertension Scientific Newsletter, compliance is defined as "... the extent to which the patient follows medical advice regarding lifestyle and nutritional modifications, as well as completing follow-up***

appointments and receiving therapy as prescribed. “Couples seeking pregnancy are commonly regarded as highly motivated in achieving pregnancy.”¹⁷ “However, *in published studies*, infertility patients demonstrate a surprisingly high treatment dropout rate from fertility clinics, ranging from 23% to 45%, with a rate even higher (82%) in an infertility service.”¹⁷

- ***Lost to follow-up:*** It is for couples who have not returned to the clinic and haven't expressed any intentions for the future; Couples who had informed the clinic of their choice to terminate clinic investigations were referred to as discontinued.
- As reported in the above-mentioned study, patient dropout rates are as high as 82%, which can be an indication of high variations in embryo billing leading to a huge revenue loss from the organization. A lot many reasons are also associated with the non-compliance showed by the patients which could be the forgetfulness regarding the embryo renewal or discard process. When patients are summoned for a follow-up or to fill out an embryo discard consent form, many of them do not show up. To summarize, a gap in patient follow up is one of the many reasons for non-adherence or non-compliance, which leads to revenue loss in the IVF clinic.
- ***According to the previous studies***⁵, the other reasons offered by the couples who were lost to follow-up or terminated the process- Changes in the decision associated with pregnancies, couples who separated/divorced, referred to other physicians for seeking IVF treatment, adopted a child also didn't go for renewing embryos or embryo discard.

Patients' decisions to refer to a new IVF center, results in the wastage of embryos that are kept at the clinic because they do not come back for renewal or the discard.

➤ ***High costs of fertility clinics:*** -

- When compared to other markets in the "United States" and "Europe", fertility clinics in India offer "IVF" at a significant discount. In India, the average cost of embryo storage "(embryo freezing)" for one cycle of IVF is between "INR 10,000 and

15,000", although this does not cover drugs, testing, or other treatments that may be required.

- With increasing infertility and sedentary lifestyle, a greater number of couples have been facing infertility issues. Hence, the IVF is helping a greater number of couples to bear a child. As discussed above, IVF comes with an added costs of approximately 1.25 lakh and it is not insured under the general health insurances as well, which has been really difficult for some segment of Indian population to be fully compliant with such high costs of IVF.
- Lack of insurance also contribute to the billing variance as some of the patient's dropout because they cannot afford to pay the renewal charges. But now IRDAI is also considering the request to cover infertility as disease in health insurance policies.

➤ **Possible errors: -**

- The possible errors that were seen during the observation are the manual errors made by the personnel's while entering the data into the organization's HMIS or EHR.
 - Out of these manual errors, billing variances are generated due to the data entry errors, and data manipulation by the personnel.
- The Standard guidelines given by the ICMR associated with the 5 years embryo freezing is not properly followed during the embryo renewal or discard process. There is also a lack of Standard Operating Procedures in the IVF clinic due to which an outstanding is generated.

7 Discussion

- The IVF market is growing at an CAGR of 13% and it can exceed the market valuation of \$1 billion dollar by 2026. Our country's IVF market is being driven by accessible and affordable health infrastructure.
- The IVF industry is gaining momentum because of the shifting of lifestyle habit which are causing disorders like PCOS and PCOD. Not only the female fertility, the growing public awareness of the male fertility in the country has projected to have a beneficial impact on the fertility market.
- The total caseload of IVF in India is 2-2.5 lakhs IVF cycles in a year, and it has the potential to do about 5-6 lakhs IVF cycles a year.
- Rising NCD's and change in lifestyle have led to lower fertility rate. As a result, women at a very young age have started to cryopreserve their eggs in order to conceive as per their convenience.
- Cryopreservation is the process by which the embryos are preserved and used them later. The embryos are mostly freeze by any two ways such as "Slow Freezing and Vitrification". After freezing process is completed, the embryos are stored in liquid nitrogen. The embryos are kept in a sealed container at a temperature around -321°F.
- Cryopreservation comes with a subscription model. This subscription needs to be chosen after the OPU extraction.
- The billing variance in the fertility business causes when the payment gets stuck, and the proposed amount does not float in the balance sheet of the business entity. Billing variance is the gap between the projected payor value and the payment made to the business.
- As we have earlier discussed in the previous section, billing variation against the embryo renewal in the respective clinics are between 62-82 percent.
- The revenue, which is standing as payment outstanding for the stored embryo inventory is as huge as 82 percent. This amount has not impacted the business before financial year 2020-21 because the primary element of the IVF business is OPU per patient.
- Embryo renewal is especially significant since the cost of storing embryos is low, and most of the procedure cost is involved during the first stage. As a result, most of the money generated by renewals directly contributes to the company's bottom line, and so has a direct impact on the company's balance sheet.

- There are numerous factors impacting the billing variance such as the non-compliance of the patients, where we generally see that the patients generally lose track of the treatment, change of mind due to previous failure rate, high cost of the fertility clinics as this is not regularized by the health insurance.
- We can generally observe the billing variance due to the operational errors such as the data entry mistakes, Not discarding embryos whose consent are provided, which also contribute a significant number to the billing variance.

8 Conclusion & Recommendations:

As we can see from the study is that how embryo renewal is important in the fertility business, as the amount of revenue generated from the renewals are directly contributing to the bottom-line of the business of the business. We have also seen that India now does an IVF case of 2-2.5 lakh a year and in the future the caseload is going to double itself, the chances of the billing variance would increase and would lead to huge amount of the revenue flowing out of the business.

As we can also see the demand of cryopreservation has increased due to the NCD's and the change in the lifestyle, which makes both the partner infertile.

The implementation of the health insurance facility in the fertility industry can really decrease the financial burden amongst the couple and make the process smooth.

These are the few recommendations which can suggested while doing the study:

- As it is one of the medical sectors which does not have standardized policies regarding the cryopreservation and renewal rate should be capped at a particular price, so that it is affordable for every section of the society.
- One of the most important factors is that bringing IVF under the health insurance sector, which will help to regularize the market and reduce the out-of-pocket expenditure.
- Implementation of proper EHR system, which can reduce the manual intervention and hence can reduce human errors such as the data entry errors.
- The EHR should be facilitated in a robust way so that it generates a monthly report of the number of renewables and the report should be further sent to the CM. In this manner, the Clinic Manager can keep a track of the pending renewables for the respective months and take necessary actions based on it.
- Proper follow up should be done with the patients before the due date for embryo renewal and discard process.
- Properly adhering to the ICMR guidelines laid down for the patients, who fails to pay after their due date and close the cases as per the ART guidelines provided.

Bibliography

1. Schiewe MC, Mullen SF. Vitrification: Fundamental Principles and Its Application for Cryopreservation of Human Reproductive Cells. In: Bozkurt Y, editor. IntechOpen; 2018. Available from: <https://www.intechopen.com/books/cryopreservation-biotechnology-in-biomedical-and-biological-sciences/vitrification-fundamental-principles-and-its-application-for-cryopreservation-of-human-reproductive->
2. Barik M, Bajpai M, Dwivedi SN. Development of new method and protocol for cryopreservation related to embryo and oocytes freezing in terms of fertilization rate: A comparative study including review of literature. Adv Biomed Res. 2016. Available from: <https://www.ncbi.nlm.nih.gov>
3. Herbon A, Lahav Y, Spiegel. A pricing scheme for a human embryo storage service as a source for a secondary market. [Elsevier Inc.]. 2020. Available from: <https://www.sciencedirect.com>
4. Konc J, Kanyo K, Kriston R, Somoskoi B, Cseh S. Cryopreservation of embryos and oocytes in human assisted reproduction. Biomed Res Int. [Pubmed]. 2014. Available from: <https://pubmed.ncbi.nlm.nih.gov>
5. Provoost V, Pennings G, Sutter PD, Dhont M. The frozen embryo and its nonresponding parents. In: Cham, Switzerland: Elsevier Inc. Humana Press: Am Thorac Soc [2020]. Available from: <https://pubmed.ncbi.nlm.nih>
6. Ahmed S, Embryo Freezing and Donation: Ethical-Legal Issues. [Website: Summer Issue]. 2018. Available from: <https://ili.ac.in/pdf/dsa.pdf>

7. In vitro fertilization (IVF). Mayo Clinic. [2019]. Available from: <https://www.mayoclinic.org/tests-procedures/in-vitro-fertilization/about/pac-20384716>
8. Revenue cycle management and contract compliance: How to analyze your payment variances blog [Internet]. Health Information Services (HIS). 2015, March. Available from: <https://blog.healthinfoservice.com/>
9. Mahoney D.E, Russell C, & Cheng A. Medication Adherence Among Women Undergoing Infertility Treatment: A Systematic Review. Int J Women's Health (2018). Available from: <https://www.semanticscholar.org>
10. Spinelli MA, Canavost GC, Brown DM. An analysis of the variation in billing charges of medical providers: causes and implications. 2007, Feb. Available from: <https://www.tandfonline.com>
11. Sabharwal G. 4 Helpful Ways to Analyze Payment Variances blog [Internet]. Medphine. (2017). Available from: <https://www.medphine.com/blog>
12. Three Smart Ways to Examine Your Payment Variances [Internet]. Health TechZone. 2016, Nov. Available from: <https://www.healthtechzone.com>
13. Clements J. Billing and Coding In Vitro Fertilization Treatment blog [Internet]. 2020 Jul. Available from: <https://www.outsourcestrategies.com>
14. Embryo freezing: What you need to know [Internet]. Medical News Today. Available from: <https://www.medicalnewstoday.com>

15. Sumant O. India In Vitro Fertilization (IVF) Services Market Expected to Reach \$1,453.0 Million, by 2026 [Internet]. Allied Market Research. 2021. Available from: <https://www.alliedmarketresearch.com>
16. Bhardwaj T. Fertility segment in India to see quick growth; onus on healthcare providers to make it accessible and affordable [Internet]. Financial express. 2021 Mar. Available from: <https://www.financialexpress.com>
17. Malcolm CE, Cumming DC. Follow-up of infertile couples who dropped out of a specialist fertility clinic. Fertil Steril. Elsevier Inc. 2004 Feb. Available from: <https://pubmed.ncbi.nlm.nih.gov>