

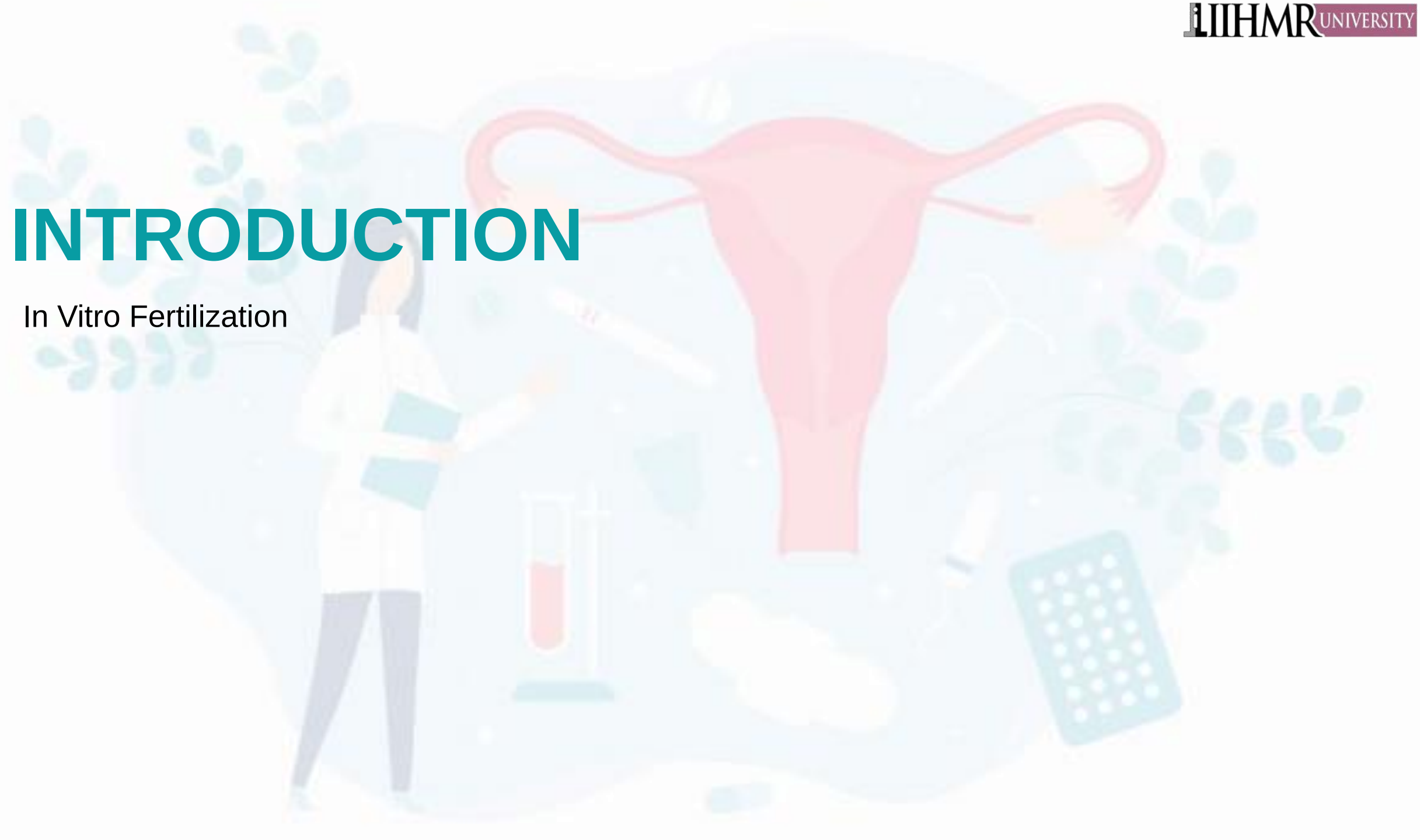
BILLING VARIANCE OF EMBRYO INVENTORY DURING In-Vitro Fertilization

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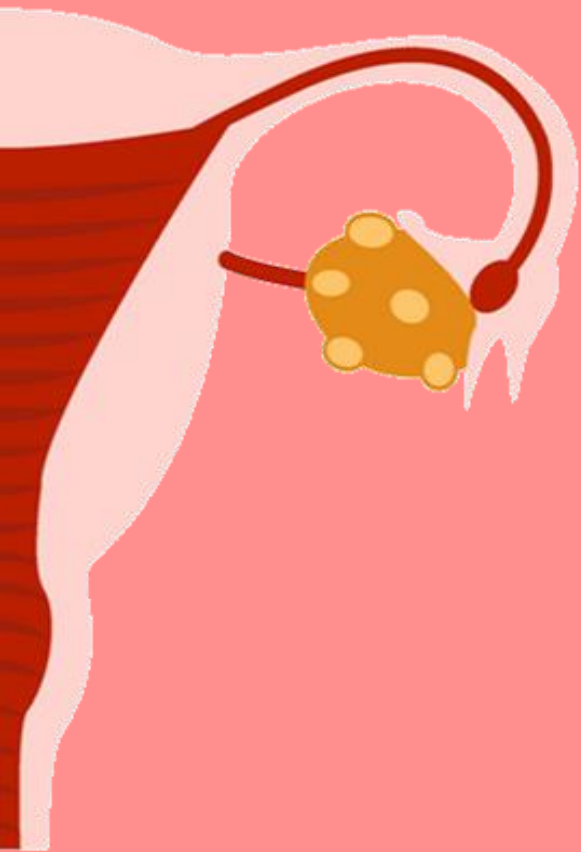
INTRODUCTION

In Vitro Fertilization

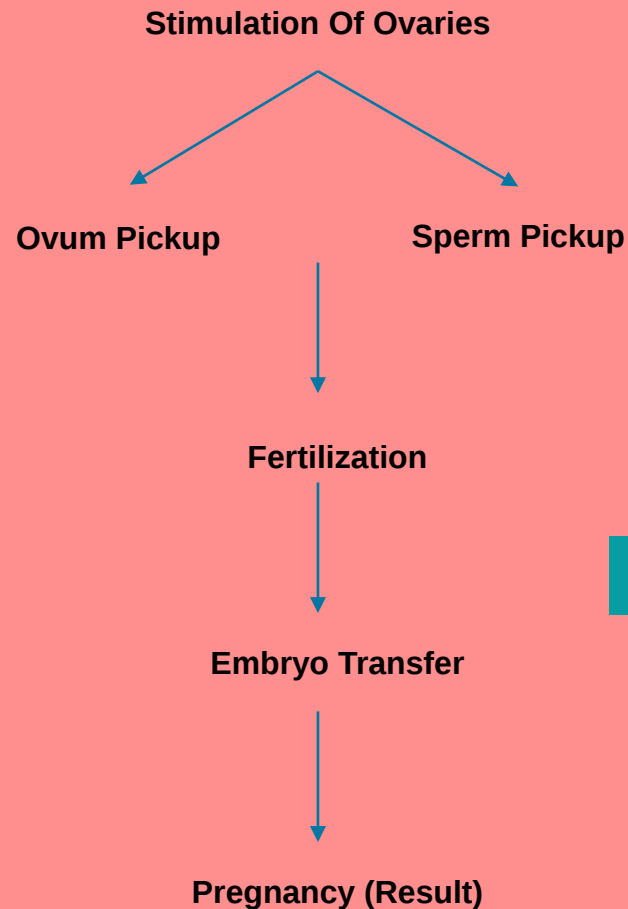


In Vitro Fertilization

IVF is defined as a critical set of clinical treatments intended to improve fertility, prevent abnormalities due to genes, an aid in conceiving a child or baby



In-Vitro Fertilization Flow process



IVF market is projected to grow at a CAGR of 13% and exceed the value of \$1 billion by 2026. In India there are about 2-2.5 lakh IVF cycles in a year.

Why In vitro Fertilization?

- Fallopian tube damage
- Uterine Fibroids
- Damaged Sperm Production
- Endometriosis
- Ovulation Problem and Disorder
- Fertility Preservation

Risks associated with IVF

- Multiple Births
- Miscarriage
- Ovarian stimulation syndrome
- Low birth weight and premature delivery
- OPU complications
- Stress

Billing Variance

How billing variance impact embryo renewal in IVF?

- ✓ 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.

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 an 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.



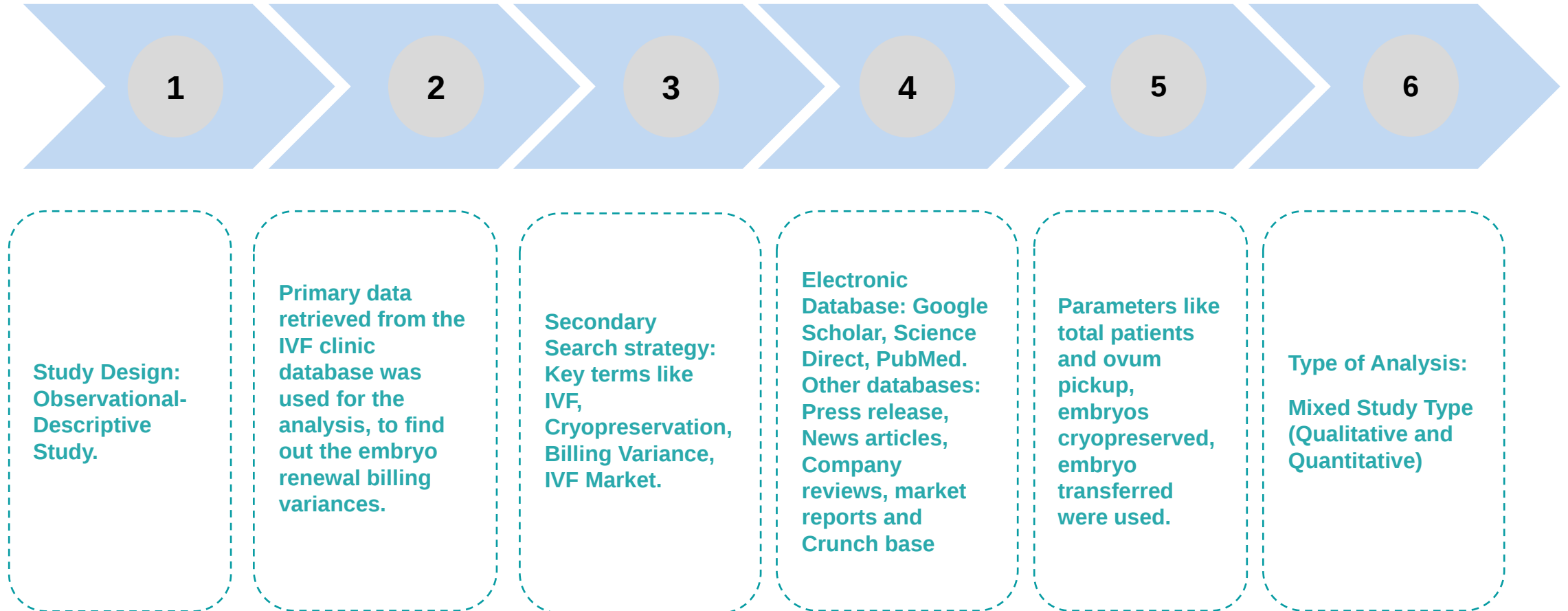
RESEARCH QUESTION

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

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.

Research Methodology



Review of Literature

Literature 1

Lahav et. al in (2020) Israel, aimed to conduct an optimal pricing policy for human embryo storage services. The suggested model reduces the unused stored embryos. 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.

Literature 2

Konc J, Kanyó K, Kriston R, Somoskyi B, and Cseh B et. al (March, 2014), Infertility and IVF Center of Buda, 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.

Review of Literature (contd.)

Literature 3

Provoost V, Pennings G, Sutter PD, and Dhont M et. al, Belgium

The objective of this study is to describe patients who at least once did not reply to correspondence of the center about embryo disposition. Feature: Patients' response behavior, 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.

Results and Discussion

Variations in embryo renewal billing and Factors impacting billing variance

Results- Embryo Freezing

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. So, clinicians now a days cryopreserve the embryos.

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

1

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.

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.

2

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

Results- Embryo renewal billing process and components used

A frozen embryo which are stored with the clinic, can remain viable for a longer period. Freezing and storing embryos are costly for the patients, 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
- Cryo tops
- 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.

Embryo renewal billing process and components used (contd.)

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.

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

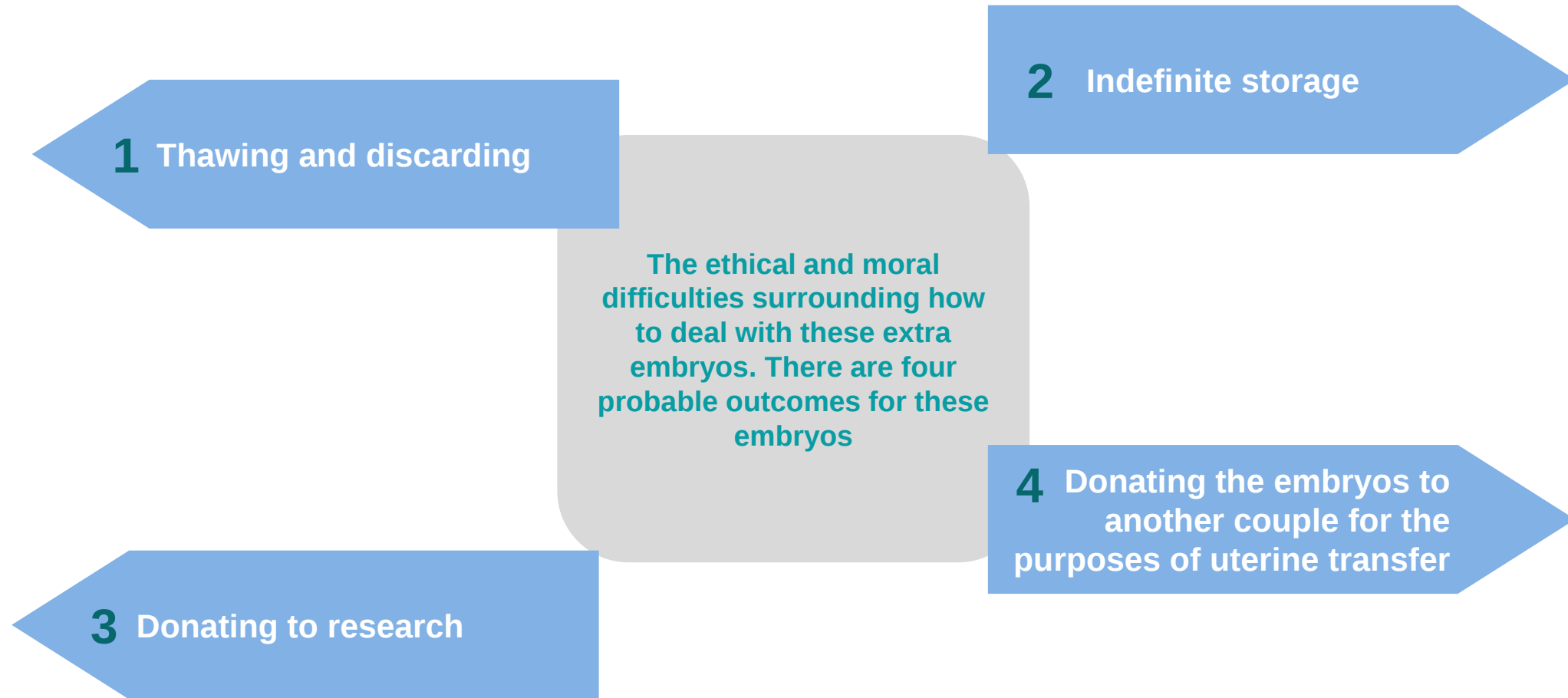
- Embryo Freezing – 9 months
- Embryo Freezing – 12 months
- Embryo Freezing – 36 months
- Embryo Freezing – 60 months

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

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.

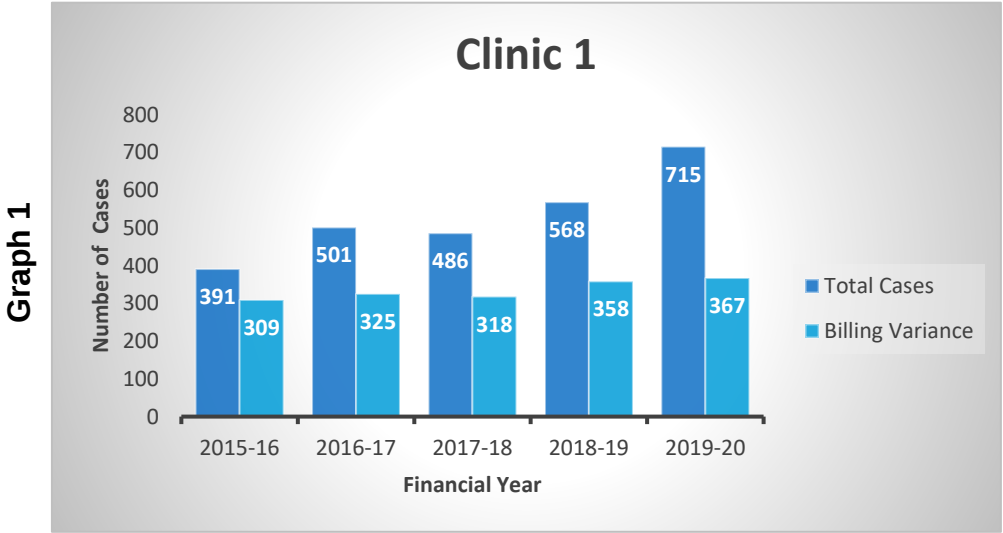
They might also consider the option of getting the embryos transferred for future childbearing/pregnancies. If neither of the above mentioned are un-wanted by the client, the embryos can be discarded with their consent.

Embryo renewal billing process and components used (contd.)

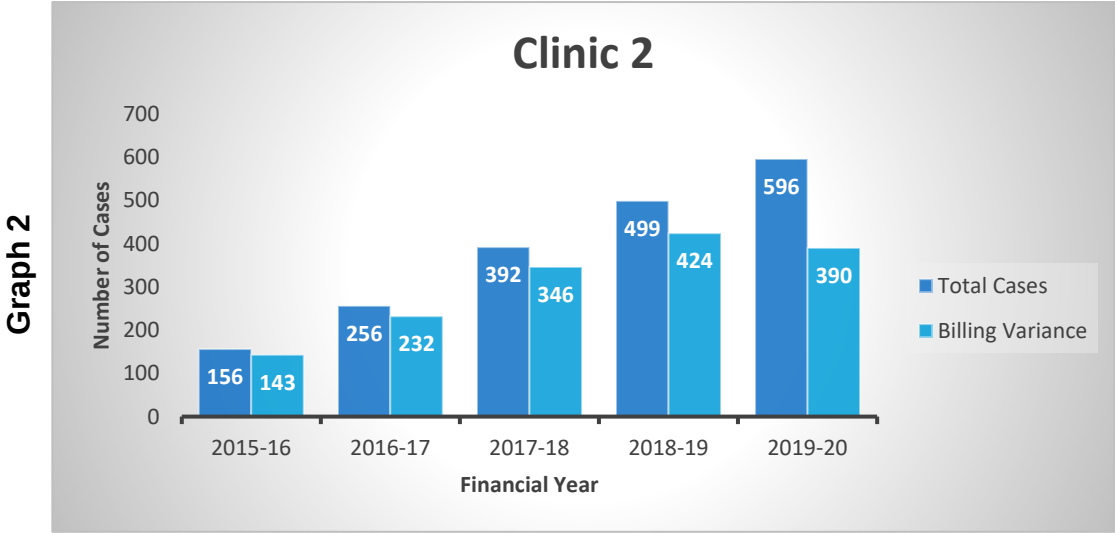


Variations in embryo renewal billing

Embryo Billing variance observed during FY 2015-16 to 2019-20 across 6 centers in South India



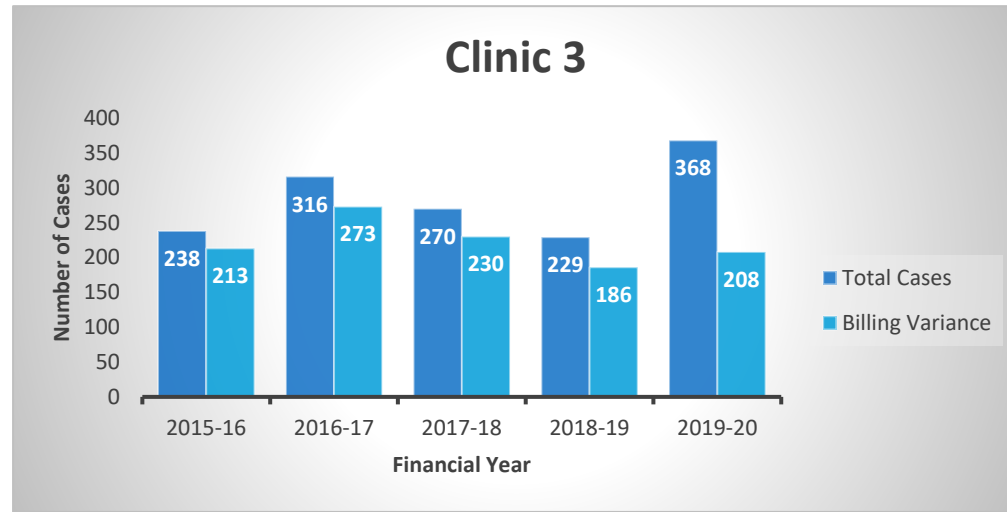
It was observed that there were total 2661 cases in the Clinic 1 taken from the FY 2015-16 to 2019-20. It also indicates that 63% billing variation in embryo renewal was found out of the total cases



From the fiscal year's 2015-16 to 2019-20, there were a total of 1899 cases in Clinic 2. It also shows that there was an 81 percent billing variance at the clinic.

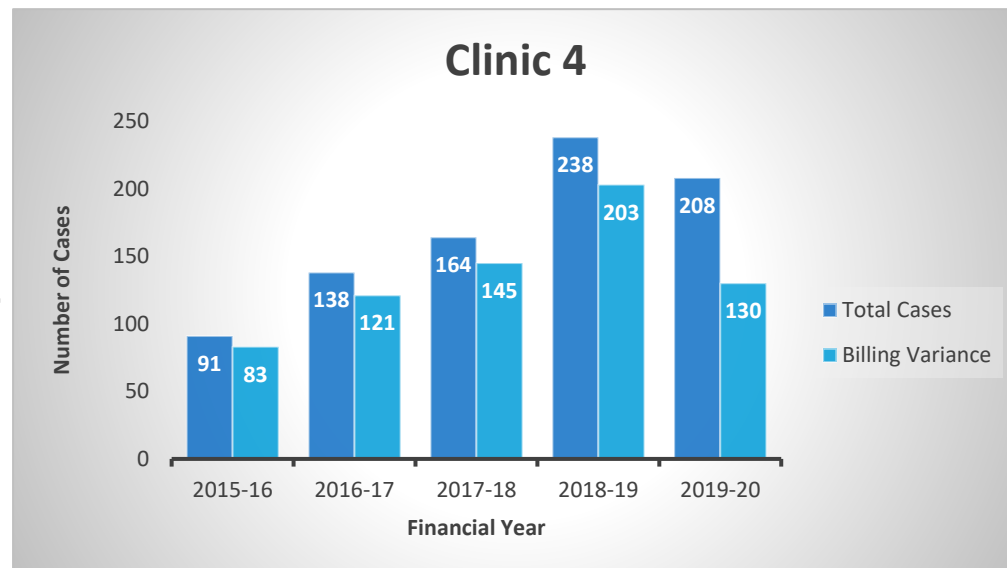
Variations in embryo renewal billing (contd.)

Graph 3



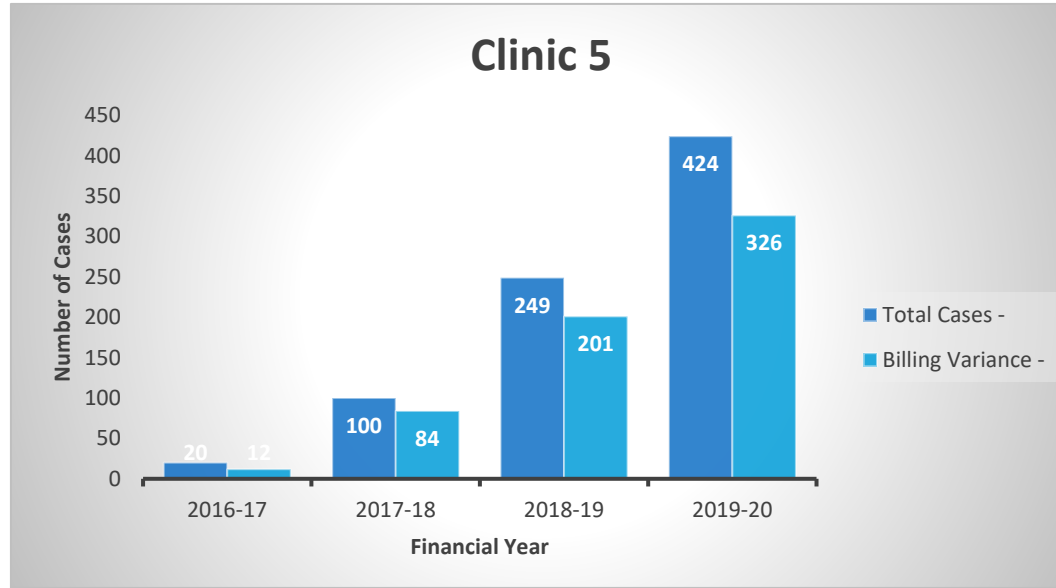
There were a total of 1421 cases in Clinic 3 between fiscal years 2015-16 to 2019-20. It also indicates that the clinic had an 78 % of billing variance from the total number of cases

Graph 4



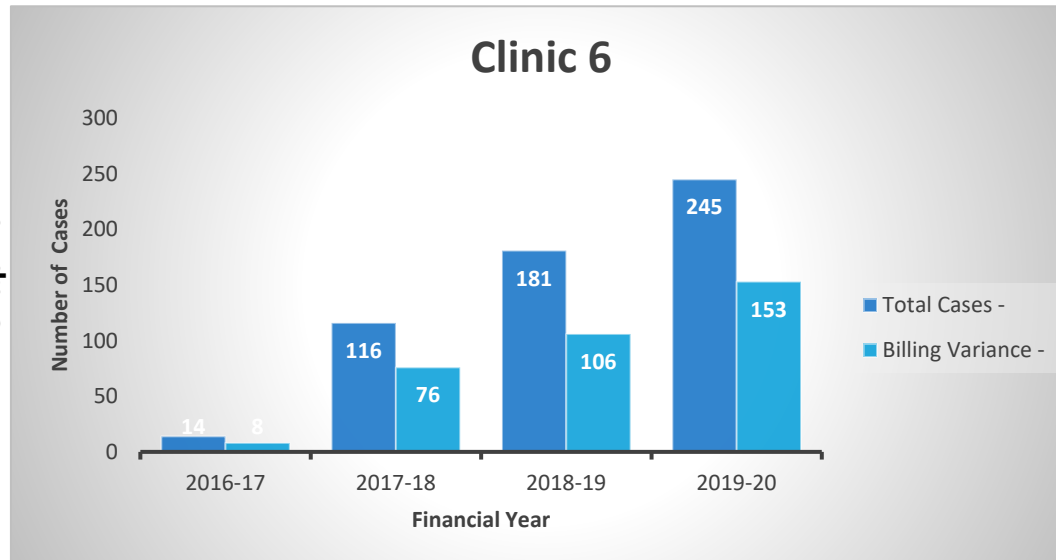
Clinic 4 had a total case load of 839 cases from the financial year 2015-16 to 2019-20. The billing variance against the embryo storage was found to be 81% of the total caseload.

Graph 5



Clinic 5 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

Graph 6



The group began its clinic 6 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

Interpretation

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

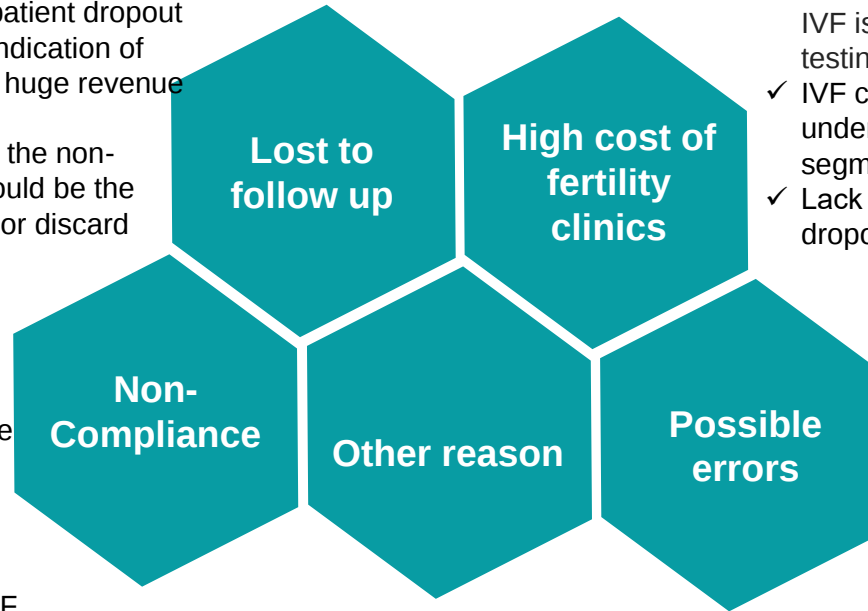
The money, which is floated in the market without being recovered, is as huge as 82 percent. This amount has not impacted the business before financial year 2020-21 because the primary element of the IVF business is OPU per patient.

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.

Factors impacting billing variance

- ✓ 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.



- ✓ The other reasons offered by the couples who were lost to follow-up or terminated the process are:
- ✓ 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.

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- ✓ 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.
- ✓ 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 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.

- ✓ 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.

Conclusion & Recommendations

A stylized illustration of a female reproductive system, including the uterus, fallopian tubes, and ovaries, rendered in a soft pink color. The illustration is set against a light blue background with faint green foliage. To the left of the reproductive system, a female figure in a white lab coat stands holding a blue folder. Below the reproductive system, there are various medical symbols: a test tube with red liquid, a white pill, a blue pill, and a blue pill blister pack.

Conclusion



- ❑ 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

Recommendations



- 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.

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