FERTILITY TREATMENT INDIA: A COST OPTIMISATION APPROACH FOR MAKING FERTILITY TREATMENT AFFORDABLE

by

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Dedication

I dedicate this study to my parents who have always provided me strength & unconditional support in my life, and my family members who have been supporting & helping me in each stage of life.

I would like to mention the person who had really inspired, motivated and supported me throughout this study & in my life journey up till now, my spouse & my business partner Dr. Sayali Kandari.

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ABSTRACT

FERTILITY TREATMENT INDIA: A COST OPTIMISATION APPROACH FOR MAKING FERTILITY TREATMENT AFFORDABLE

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Infertility is a reality for more than 15% of couples globally. In India, only a fraction can access tertiary level care with specialty hospitals catering to couples. A large private segment has emerged in India and affordability has become a constant factor in allowing patients to access care with acceptable success rates of 40% average per cycle. Our Quantitative research work has surveyed 80 (eighty) experts in the field nationally and a Panel of experts has been consulted to provide a detailed quantitative estimate of cost optimization methods in Fertility treatment. This work is seminal in nature and is the first of its kind in India where government support and research work is scant on cost optimization for Fertility Centers in India. The results and discussions fore with can be used to build more robust operations and improve access to care to aspiring couples.

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CHAPTER I:

INTRODUCTION

1.1 Introduction

The most essential basic purpose of every life form is survival, reproducing and safeguarding your own genetic offspring.

Every human couple dream of starting a family at some point in their life, each human being has the basic right to reproduce and have an offspring but in the current times having an offspring has become a special privilege that a large section of the society cannot undertake due to various factors, one of which is infertility which is, not having the natural ability to have children.

Infertility rate has drastically increased worldwide affecting approximately 15% of the couples globally out of which 25% are attributed to India itself (World Health Organization, 2018).

For developing countries like India, infertility treatment cost is one of the major issues which restrict the penetration of infertility treatment and deprive the economically challenged section of the society.

According to the Indian census report (2011), The TFR (Total fertility rate) has declined drastically from 5.4(Year 1971) to 2.5(Year 2016) in rural India and for urban India the TFR declined from 4.1(1971) to 1.8(2016) owing to population control efforts. The future has thrown more challenges in treating infertility as this data is correlated to

rising age of conception, possibly leading to even steeper rates of infertility in this century (Purkayastha, 2021).

There have been various technological advancements which have increased the chances of pregnancy, but the infertility treatment cost is still a major concern and hurdle, still depriving a large section of the Indian population from accessing the infertility treatment (Shahin, 2007; Schurr, 2018).

In India infertility treatment is still not covered under insurance by the major insurance providers (Majumdar, 2021).

Very few organizations like Indian Railways and some handpicked private companies and some foreign multinational companies are providing some financial reimbursement / support to their employees for infertility treatment, but the financial support is just a fraction of the total cost of the infertility treatment (Shah, 2015).

A tertiary center study conducted (Arakkal, 2020) to see the cost differentiation between a conventional ART (Assisted reproductive Treatment) to a low cost ART with limited resources show that conventional ART (Assisted reproductive Treatment) was 50% higher in cost as compared to low cost ART (Assisted reproductive Treatment) but in terms of CPR (Clinical pregnancy rate) (per embryo transferred), the conventional ART had 40% CPR (Clinical pregnancy rate) and the low cost ART (Assisted reproductive Treatment) had 17%. A notable fall in CPR (Clinical pregnancy rate) rate is observed for low-cost ART (Assisted reproductive Treatment) thus there is a need for further research and innovation in low-cost ART to increase the CPR (Clinical pregnancy rate) comparable to conventional ART (Assisted reproductive Treatment) (Singh, 2021).

Primary infertility among Indian women is inversely proportional to the education level and living standards. The study also attributes the increase in infertility in urban cities to lifestyles and environmental parity. In LMICs (Low- & middle-income countries), there is a need for intervention and guidance from a higher body like WHO (World health organization) to raise the standards of quality, improve access to infertility care and general social acceptance of infertility treatment (Chiware, 2021).

In India Infertility is still related to a lot of social stigmas thus the infertile individual / couple struggle to socially accept that they would need medical assistance for having children. As per global market insights market report, a major roadblock in infertility treatment is the deterring high price of the various procedures and multiple social barriers and inappropriate infrastructure (Ugalmugle, 2020).

Overall, the support and role of Indian government via the public sector is very limited and not up to the mark in assisted reproduction sector. The public sector lacks in even conducting basic diagnostics, investigations and the basic services are seriously insufficient. Insufficient infrastructure, improper management and absence of proper training, knowledge and appropriate protocols are hampering the fertility service delivery in public sector (Agarwal, 2020).

Another serious issue is the private practices conducted by public health doctors thus not able to give sufficient time and attention in their public health setup. Apart from not having proper regulations, the attention of the public doctor is also divided due to involvement in other health issues (Widge, 2009).

There is a dire need for practical and economical cost management along with optimizing and drafting proper regulation for the fertility services currently provided. Significant work needs to be done in providing proper information to people and appropriate counseling of the child aspiring couples and creating mass awareness about the whole topic to the public at large (Sethi, 2020).

Another report suggests that the cost of total infertility treatment is high, though the need for fertility treatment has increased over the time but with the innovation in advanced technology and better medicines has further increased the cost and reduced the access to people due to this high-cost barrier (Teoh, 2014).

Thus, there is an urgent need to explore low-cost fertility treatment options which can help even small clinics with very limited resources to provide the service. There have been some initiatives towards this, but more research and emphasis need to be given to this critical topic (Chiware, 2021).

There is a need to make fertility treatment affordable in India so this is an attempt of finding different ways fertility centers are optimizing the treatment cost, the following information can be used to create a new business model for low-cost fertility treatment which can be undertaken by the government or the upcoming generation of social or health entrepreneurs. One of the major problems with the literature review is the lack of sufficient published data on infertility treatment cost and various measures to bring down the cost (Njagi, 2023).

The ART (Assisted reproductive techniques) Regulation Bill 2021 has been passed by the Indian government in the parliament and the implementation has started in full swing in India (Tank, 2023).

It is a common complaint among fertility professionals from conference and panel discussions in Indian Society of Assisted Reproduction Conference 2023, that the bill regulations and guidelines are not in sync with the current industry practices and thus lack practicality thus it will face a major protest from the infertility practicing doctors, clinics and companies. These regulations and guidelines will drastically change the way infertility industry functions adversely affecting the overall infertility treatment cost and the brunt has to be borne by the child aspiring couples who need treatment.

If we consider overall medical treatment history, infertility treatment is relatively new in the timeline, with the Birth of first IVF baby in 1978. Till date, the overall benchmark success rate for infertility treatment is 35-40% live birth rate per patient per embryo transfer in top performing units across the world. The industry segment is still evolving and with the fast-changing overall fertility health of the people due to various factors like sedentary lifestyle, junk food, genetics and many more the problem is going to get more complicated than ever before (Majumdar, 2021).

Lack of sufficient published data on infertility treatment cost and measures to bring down the cost is a major hurdle. At present there are just a handful of companies manufacturing IVF lab consumables nationally and those products in terms quality/performance and service are still catching up with their international competitors due to various market limiting factors (Patel, 2022).

With some of the major foreign brands in acquisition spree the cost of laboratory consumables would be restricted to either a monopoly or a duopoly competition in the infertility industry hence the eventually the consumables cost will increase affecting the cost of overall cost of infertility treatment. With the Total fertility rate of India declining contributed by various factors out of which one of the major factors is cost, thus very low penetration in the small towns and villages of India (Ernst & Young LLP, 2015).

Government focus on infertility treatment is missing and with recent ART (Assisted reproductive techniques) Regulation Bill 2021 it is crystal clear that infertility industry is not the preferred medical segment for the government and no help in form of subsidy or cost optimization can be expected in near future (Tank, 2023).

Thus, there is a greater need to identify the most feasible steps by which the Infertility treatment cost can be reduced, and by compiling these steps to create a summary guide of steps which can provide new business opportunities for the individual aspiring clinical fertility specialist to set up an Assisted Reproductive Services clinic or for a corporate entity to explore and develop a low-cost infertility treatment business model, which can be easily replicated across India.

1.2 Research Problem

The problem of infertility is rising very fast in India and contrary to the popular belief even the rural population is severely affected by it, but they do not have access to care and infertility treatment being expensive is the top deterrent for approaching treatment as reported by the market report (Ernst & Young LLP, 2015).

Current literature is pointing directly and indirectly towards the high cost of infertility treatment and various not so concrete and unsuccessful attempts to address the same. The Indian government is still struggling to provide basic healthcare to the lower income section of the society who cannot afford it, there is very little or no support of governmental healthcare agencies towards infertility treatment for the masses. The recently passed law, The 'Assisted Reproductive Technology (Regulation) Bill (2021)' is focused on defining the procedures and policies and does not say anything about affordability or improving the access to care. With the total fertility rate falling drastically in Urban and Rural India with high cost being a major factor, some focus is required to address the issue (Patrizio, 2022).

The primary research method would be literature review to identify current modalities of cost reduction in reproductive and allied health services which can be feasibly accommodated in Assisted Reproductive Services. Qualitative survey-based methods would be most suitable to conduct research to gather preliminary data via interviews from the various fertility clinics across India regarding their real time attempts, steps and methods to reduce cost in their personal health practice. The survey data shall give insights on current scenarios and feasible steps that various fertility clinics in India are undertaking to address the high cost for taking infertility treatment.

ART (Assisted reproductive techniques) Rules 2022 have led down strict regulations for fertility treatment including third party reproduction services in India. Third party reproduction involves use of either male or female donor gametes or gestational surrogacy involving a third person apart from the commissioning couple who shall be donating the same with financial incentive in case of donor gametes and altruistic with a person of familial ties in case of surrogacy. The laid down sections limit the division of oocytes or sperm retrieved from the donor to be used only once in their lifetime and to only one recipient couple. This change can double the cost of one in-vitro fertilization cycle from an average of Rs 2,50,00 to up to Rs 5,00,000.

The entire Indian IVF fraternity is now faced with the daunting challenge of keeping the infertility treatment costs down without compromising on the average success rate of 40% worldwide.

The ART (Assisted reproductive techniques) Regulation Bill 2022 has recently passed by the government and implementation has begun. Furthermore, the bill regulations and guidelines are not in sync with the current industry needs / practices and thus lack practicality, thus currently facing major protests from the infertility practicing doctors, clinics and companies and the whole fraternity. These regulations and guidelines will adversely change the way the infertility industry functions, affecting the overall infertility treatment cost and the brunt has to be borne by the child aspiring couples who need treatment.

Lack of sufficient published data on infertility treatment cost and measures to bring down the cost is a major hurdle. At present there are just a handful of Indian manufacturing companies making very few IVF lab consumables and Medicines and

some of these products lack proper certification and the quality/performance of the product is not at par with foreign brands (Li, 2024).

With some of the major foreign manufacturing brands in acquisition spree in India, the cost of laboratory consumables would increase due to an oligopoly competition in the infertility industry giving little to no incentive for controlling consumables cost, affecting the overall cost of infertility treatment.

With the Total fertility rate of India declining contributed by various factors out of which one of the major factors is cost, currently there is very low penetration in the small towns and villages of India.

1.3 Purpose of Research

The objective of researching methods of cost optimization is to improve market access to the population who needs medical treatment to conceive. These populations are varied in their socioeconomic status and geography and the limitations imposed by the current small to medium size vs. corporate chain business models are different yet affect the potential patients in the below ways.

1) Non-Transparency of cost and too many variables before pricing is determined.
2) Lack of knowledge about working of IVF units and about accessing care.
3) Non sustainable financial practices of IVF Units run by doctor entrepreneurs.
4) IVF Center lack of financial and cost optimization audits to ensure survivability and thus no benefit pass on to patients.
5) For profit corporatization of sector leading to added operational and overhead costs to patients.

The proposed research plan is to run a detailed questionnaire across the medical fraternity of IVF industry to understand their cost reduction methods and current constraints.

Further these will be tabulated and a literature survey of current cost optimization methods by users as well as via published literature will be made and these will be put in the workflow of the current IVF setups.

An IVF center various cost optimization factors & methods undertaken shall be discussed will be run through multiple scenarios to rank the best to least effect methods.

1.4 Significance of the Study

The Survey is first of its kind ever conducted in the field of Fertility in India evaluating the attitudes and practical steps taken by Fertility Centers in India. The results would allow us to compare practice considerations and Fertility Center stakeholder's preferences for cost optimization in managing the hospital fiscals.

The study will enable entrepreneurs or even the corporate setups currently providing Fertility treatment with the basic understanding of how stakeholders make cost optimization decisions and where the bulk of their interest in change lies. Where the stakeholders do not wish to change the input costs due to quality or other reasons and whether the practices are correlative to the current practices in medicine or other allied fields in healthcare space.

If the practices are too incongruent to the industry backed and proven methods of financial optimization, a relearning phase and the correct process with a teaching channel has to be provided to the IVF center / Fertility Units so they can implement better practices.

The current view when presented alongside with survey results and compared to correlative methods in healthcare are presented, it will create the path forward for designing a teaching or learning module for the providers and also maybe small service sector to provide these services which may crop up due to lack of time and improved outcomes provided by such a targeted intervention.

CHAPTER II:

REVIEW OF LITERATURE

2.1 Introduction to fertility Treatment

2.1.1 The History of Infertility management

In vitro fertilization was conceived when infertility started finally to be treated as a medical condition rather than having a divine cause or as 'punishment' for previous life's sins. Such removal of superstitions by highly deserving doctors and scientists in the 19th century who decided to research and work on such a taboo subject is the reason the Fertility doctors and scientists of today exist not to mention the millions of children born and the gift of parenthood to multiple million people on this planet.

In 1800s the following discoveries lead to increasing knowledge of fertility. In 1827, existence of ova, or eggs, in the female body was confirmed. In 1843 scientists ascertained that conception occurs when sperm enters an ovum. Research in fertility hence began (Sharma, 2018).

Spallanzani was a pioneer scientist who discovered spermatozoon contained nucleus and cytoplasm in 1779. He later established for the first time that the embryo develops as a result of physical contact between the egg and the sperm. And with this information he successfully inseminated dogs (Tullia, 2022).

2.1.2 Artificial Insemination

The only way was to treat infertility was via female surgery or so was thought by clinicians and scientists. A Scottish surgeon Dr. John Hunter in late 1770s first reported theoretically that artificial insemination can be applied in a woman.

The various discoveries that have led to the use of artificial insemination have occurred from different corners of the globe over an expanded period of a century's time. In Italy, Spallanzani, the pioneer scientist proved that sperm can be frozen for the first time ever and showed thawing viability in spermatozoa frozen in ice. On the other hand, Carl Ernst Von Baer, discovered the mammalian ovum, spearheading the discovery that has led to all modern fertility medicine for female egg development in 1827.

Meanwhile, In Russia, Ivanow in 1922 established artificial insemination as a procedure in animals and this research advanced science in AI in western countries. Artificial insemination in animals thus was established and practiced for many years before this procedure was attempted in humans (Tullia, 2022).

Artificial insemination in women has a checkered history. Reports of early use describe a clinician Dr. Simms trying procedure 55 (fifty five) times on 6 (six) different women, without tracking ovulation in these women and hence only one attempt leading to miscarriage was the output. For doctors and the society alike, it took much longer to accept that male infertility could be the reason for a couple to not conceive and the concept of male infertility started taking shape in 19^{th} century (Southern California Reproductive Center, 2023).

2.1.3 Artificial Insemination with donor semen

Where the history of male infertility being treated was with bumps and bruises, the the first recorded case of artificial insemination by donors is even worse. In 1884 a pompous Dr. William Pancoast secretly treated a woman's infertility by inseminating the woman with sperm obtained from a medical student. Patient consent was not sought or given. It was only after 25 years of doing this incidence come to light after the child born was well an adult. A cancelled license, high level condemnation is the background behind the first donor insemination but today under regulations, laws and consensual documentation, Donor insemination is a high success and one of the most effective treatment option for couples with male partners who have azoospermia (zero or no sperm count in the semen sample) and do not wish to undergo surgical retrieval or pass on any genetic disorders to child born (Yuko, 2016).

Human Artificial insemination first report was published by Guttmacher in 1943. After that artificial inseminations were used as treatment plan only in cases of male physiological and psychological dysfunction. Around 1909, artificial donor insemination started gaining acceptance (Jouannet, 2022).

2.1.4 Hysterosalpingography (HSG)

Hysterosalpingography (HSG) is a procedure conducted under X-ray contrast with dye fluoroscopy. It is used to evaluate the endometrial cavity and fallopian tubes. It began as a standard test in the workup of infertile couples for tubal patency evaluation. However, its lack of definitive diagnosis due to non -visualization, lack of graded assessment and high failure rates due to cramping of tubes leading to almost 25% high false positives, makes this test's relevance in today's time questionable for private practitioners where accurate diagnosis is of utmost importance.

Hysterosalpingography (HSG) reports are supposed to include information about uterine size and filling defects with findings suggestive of fibroids, polyps, adhesions, and septa (Acholonu, 2011).

However, in today's era of 3D/4D Sonography and diagnostic laparoscopy and hysteroscopy, Hysterosalpingography (HSG) has become an out-dated tool.

2.1.5 Sonosalpingography (SSG)

Compared to hysterosonogram, the sonosalpingogram is a more updated addition for evaluating uterine defects and tubal patency. Many studies demonstrate superiority of SSG over HSG in uterine and tubal evaluation in recurrent pregnancy loss and as uterine screening prior to IVF cycle.

Sonosalpingography (SSG) has lower sensitivity and specificity compared to diagnostic laparoscopy and hysteroscopy for evaluating patients however in patients with a low time of infertility and other known factors leading to infertility like impaired semen parameters, Sonosalpingography (SSG) can be an acceptable first line screening test before ovulation studies or intra uterine insemination (Pujar, 2010).

Guidance of treatment through Sonosalpingography (SSG) findings like recent advances in endometrial receptivity and micro biome evaluation which adds to extended time and cost of treatment can lead to better outcomes in patients and reduce time to pregnancy (Kandari, 2024).

2.1.6 Concept of Cryopreservation

Artificial insemination gave an impetus to developing and perfecting the methods of collection of sperm within the semen components and its long-term preservation and retrieval for use. In 1866, Mantegazza, theorized the need of banks for frozen human sperm.

During the Gulf war crises of 1992, army men froze their sperm samples before leaving for battle and this vision came to a reality. Polge et al. did groundbreaking work with glycerol as a cryo-protectant creating a potent semen cryopreservation media which till date has not been significantly changed from the original formulation.

Sherman et al, froze sperm using glycerol in dry ice in 1953. Thawing protocol was perfected by Sherman and he theorized and demonstrated that thawed sperm should retain their fertilizing potential and allow normal egg growth post fertilization which then led to the first successful human pregnancy with frozen sperm. With these improvement sperm banking came into existence (Sharma, 2018).

With eggs and embryos cryopreservation was more difficult to achieve and developing these techniques have played a lion's share in the growing success of IVF. The first successful pregnancy using previously frozen eggs was reported in 1984.

The first live birth using a frozen embryo was reported in 1999. However, the first true cryopreservation baby born was in India in 1978 and world's second IVF baby Kanupriya Agrawal born in Kolkata, India.

Today these cryopreservation procedures are not just used for storing spare embryos but also for optimizing outcomes by separating the ovarian stimulation and egg retrieval procedure from embryo transfer and reducing many of the risks of Ovarian Hyper stimulation Syndrome as well as frozen embryo transfer reducing risk of low birth weight that is associated with fresh embryo transfer IVF (Southern California Reproductive Center, 2023).

2.1.7 In vitro Fertilization (IVF) Revolution

The next large frontier crossed in the revolution of IVF was the identification of hormones involved in reproduction. The 1920s and 30s were all signified with discovery of the hormones, progesterone, estrogen, and testosterone and subsequent roles in reproduction and pregnancy. Various pharmaceutical companies which are mega block buster companies today with development of chemical hormone substitutes and supplements in 1940s, today a standard part of infertility treatments.

On 25 July 1978, the first IVF baby was born at Oldham and District Hospital in Greater Manchester United Kingdom. Named Louise Joy Brown, her birth changed everything. IVF as a new technology suddenly found a large wave of positive public opinion and hope ignited in the hearts of many couples desperate for a family. Today after only 36 years of progress, the technology has advanced to blastocyst stage, improved implantation via advanced modalities of hormonal supplementation and sonographic and surgical evaluations and corrections and healthy babies are carried to full-term gestation with success rates of 35-40% per cycle (Sharma, 2018).

2.1.8 In-vitro Fertilization – The Indian Scenario

India is home to the World's second IVF baby and the first cryopreserved embryo baby in the world . The pioneer who was shamed and ostracized by the medical fraternity in India and who later died by suicide, Dr. Subhas Mukherjee was the Indian scientist and physiologist from Kolkata who announced the birth of Kanupriya alias Durga with IVF and cryopreserved embryo on October 3, 1978.

Later once discovered, the work of doctor Subhash Mukherjee was submitted in the form of a report to the Government of West Bengal, India. The work was presented at the Indian Science Congress in 1978 and was also published in 1978 Dr. Mukherjee. He developed novel techniques like the use of gonadotropins for ovarian stimulation, cryopreservation techniques, freezing, storing and thawing the embryos. The work and his genius are an absolute marvel, and it was a shame upon the Indian Government and Indian Gynecological groups who did not allow him to get recognition or validation at the time (Bharadwaj, 2016).

It was later in 1982, that the Indian Council of Medical Research (ICMR took over the infertility project which was led by T.C. Anand Kumar and Indira Hinduja at its Institute for Research in Reproduction known now as the ICMR-National Institute for Research in Reproductive Health at Mumbai. As a result, India's second test tube baby, 'Harsha', was born on August 6, 1986. Harsha was known erroneously as the first test tube baby for many years until T C Anand Kumar found Dr. Subhas Mukherjee's notes and publicly gave Dr. Mukherjee posthumous recognition (Mukherjee, 2024).

From 1980 till now the 2020s, the rise in infertility treatment has exponentially risen with a CAGR of 20% or more every year. Due to this ever-increasing demand for IVF, the IVF clinics in the country are mushrooming rapidly and before the ART bill, without much regulation or oversight.

Safety concerns started taking center stage a few years ago on fertility services in India when questionable news reports of unethical practices came to the fore like very old women aged 65 and above were provided conception through IVF or when surrogacy was offered as an option to high income women and their families effectively creating a 'womb-on-rent' market not just for Indian patients but also overseas patients who would come to India for fertility services at a relatively low cost and with no regulations.

For oversight and regulation, the ICMR developed the National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India in 2005, later reworked on into the Assisted Reproductive Technology Regulation Bill, 2017 and Surrogacy Regulation Bill, 2016. However, the actual bill passed in 2021 finally today, known as the Assisted Reproduction Technology Act 2022 and The Surrogacy Regulation Act 2021.

Today the entire infertility treatment is regulated under the amended ART Bill 2022 recently launched in Jan 2022 and undergoing various gazette modifications and update. As the entire industry is in a furore of implementation, the rise of Quality Management Systems approach is being driven by industry and small regional players alike, leading, overall, to an overhaul and improvement of Reproductive Medicine disbursement to patients (Tank 2023).

2.1.9 Gonadotropin use in Fertility Treatment

Human Chorionic gonadotropin (hCG) obtained from placental extracts was the initial gonadotropin product available for commercial use, closely followed by animal derived pituitary gonadotropin extracts like equine or porcine. Using this two-step protocol emerged and involved ovarian stimulation using animal gonadotropins, followed by ovulation triggering using hCG. The major limiting factor was immune reaction due to animal products and hence it could be used for only a short half-life. This prompted the development of human pituitary gonadotropins (Plant, 2022).

In human pituitary gonadotropins obtained mainly from human cadavers or menopausal women urine, the major limiting factors were supply issues and the risk for CJD (Creutzfeldt–Jakob disease) in human urinary derived gonadotropins (CJD is a disorder of the brain leading to dementia – loss of memory). However, today due to high purification methods leading to highly purified urinary gonadotropins as well as the emergence of recombinant technology, today human pituitary gonadotropin has been withdrawn from the market (Hsien-Ming Wu, 2020).

Till data urinary human menopausal gonadotropin (hMG) preparations are developed, and enhancements in purification techniques now allow a fixed dose of gonadotropins follicle-stimulating hormone (FSH) with or without luteinizing hormone (LH) activity. The first reported pregnancy resulting from ovulation stimulation with human menopausal gonadotropin (hMG) and ovulation induction with human Chorionic gonadotropin (hCG) was documented in 1962, and this product is now part of modern protocol for ART (Al-Inany 2003).

Improvements in immune-purification techniques facilitated the removal of luteinizing hormone (LH) from human menopausal gonadotropin (hMG) preparations, but there were still unidentified urinary protein contaminants persisted as an issue. Later, monoclonal follicle-stimulating hormone (FSH) antibodies were utilized to produce highly purified FSH with minimal luteinizing hormone (LH) activity with low amount of unidentified urinary proteins, enabling the formulation of smaller injection volumes suitable for subcutaneous administration.

Development of recombinant gonadotropins removed the challenges connected with gonadotropins derived from urine donations, such as batch-to-batch variability and a finite donor supply but the cost has still been a contentious issue. The first recombinant human FSH molecules obtained marketing approvals in 1995 (follitropin alfa) and 1996 (follitropin beta) they exhibited superior purity and a more homogenous glycosylation pattern compared to urinary or pituitary FSH. Subsequently, recombinant versions of LH and human Chorionic gonadotropin (hCG) were developed, and biosimilar versions of follitropin alfa have received marketing authorization.

Recent advancements include a recombinant FSH produced using a human cell line and a long-acting FSH preparation. These state-of-the-art products are administered subcutaneously via pen injection devices. However, randomized controlled trials over recent years with highly purified urinary formulations compared to recombinant formulations show no difference in number of pregnancies and live births allowing IVF hospitals to use either for ovarian stimulation (Lunenfeld, 2019).

2.1.10 Urinary Gonadotropin use in Fertility Treatment

Researchers Ascheim and Zondek in 1927 noticed in pregnant women's blood and urine that there was a substance that stimulated the gonads, which was later identified as human chorionic gonadotropin (hCG) by Seegar-Jones and his team in the 1940s, after it was shown to be produced by the placenta.

In 1929, researcher Zondek from his and Smith's work discovered two hormones made by the pituitary gland that stimulated the gonads. Thus follicle-stimulating hormone (FSH) and luteinizing hormone (LH) were discovered. They hinted at the potential of gonadotropins to treat infertility leading to later formation of pure gonadotropin therapies. These developments have helped millions of people having infertility have children (Lunenfeld, 2019).

2.1.11 Recombinants Gonadotropin use in Fertility Treatment

Recombinant Bioengineered biological are proteins created through DNA technology that involves biological methods to generate complex drugs that are not feasible to make with chemical synthesis. Bioengineered gonadotropins were created to bypass the challenges associated with the initial urine-derived gonadotropin products, as these bioengineered ones can be manufactured in large quantities with high purity and consistency in their composition. Similar to human menopausal gonadotropins, these bioengineered or now known as recombinant products are also effective for treating infertility in both males and females (Lunenfeld, 2019).

2.1.12 Advances in Fertility Treatment

The rapid and exponential progress of assisted reproductive techniques in treating infertile couples is one of the most remarkable achievements in the field of medicine worldwide. Robert Edwards and Patrick Steptoe won the Nobel Prize in 2010 in Physiology or Medicine for the founding of IVF. The extensive improvement of techniques in assisted reproductive technology has created possibilities for addressing fertility issues that were once thought to be insurmountable.

Infertility, once an unspeakable social stigma, was turned into a solvable medical problem with rapid advancements in science. Within our organic, biological and mammalian roots lies the basic need of longing to have a biological offspring and the desire to have a family successor and the founding of IVF made dreams of millions of couples come true and is still performing miracles on a regular basis today.

2.1.13 Intra Cytoplasmic Sperm Injection (ICSI)

Intra-cytoplasmic Sperm Injection (ICSI) involves an embryologist manually injecting a sperm into an egg under a microscope, utilizing specialized tools for micromanipulation. This technique was introduced in 1987 and its first successful pregnancy from ICSI was in 1992.

Intra-cytoplasmic Sperm Injection (ICSI) has emerged as a crucial method for addressing various forms of infertility related to male factors, with poor sperm quality being the most common reason for infertility. It proves especially beneficial for cases

where a man has a very low sperm count, abnormal sperm shape, or issues with sperm's ability to penetrate the egg for fertilization (O'Neill et al., 2018).

2.1.14 Third party reproduction and gamete donor use

In 1987, a significant advancement in in vitro fertilization (IVF) was achieved with the introduction of publicly accessible donor egg programs. By this time, sperm donation services had been around since 1970, being utilized for both artificial insemination and IVF procedures.

However, the process of incorporating egg donation into IVF was more gradual. The initial successful pregnancies resulting from egg donation took place in 1983, and since then, more than 50,000 babies have been born from donated eggs.

IVF with donor eggs is a highly successful method, particularly beneficial for women facing challenges with low ovarian reserve or poor egg quality. This technique has made parenthood achievable for numerous women who would have otherwise been unable to conceive (Greenfeld, 2015).

2.1.15 Pre-Implantation Genetic Testing (PGT)

One of the top reasons Genetics is making a large footprint in Fertility is the problem of multiple births.

When IVF began and success rates were understandably low due to on-going medical research being at the early stages, it was customary to develop eggs till three days in the laboratory and transfer more than one, sometimes up to four or five embryos to ensure pregnancy resulted. This practice significantly contributed to the public's association of IVF with the birth of twins and multiples.

In most cases multiple births after a long hiatus of infertility can be a joy; however, the heightened risks for both the mother and the babies during pregnancy and delivery are substantial and not suitable with modern practices and the high risk pregnancy rates.

Multiple pregnancies are always considered high-risk pregnancies, and whenever feasible, medical practitioners aim to minimize these risks. In-spite of widespread acceptance of IVF there has been instances of public criticism and media attention. A prime example is Nadya Suleman, better known as "Octomom," who became famous after giving birth to eight children in 2009 following an IVF procedure that involved transferring twelve (12) embryos.

This of course was an extremely ill-advised departure from best practices on the part of Nadya’s fertility doctor. Today, pre-implantation genetics can select the genetically normal embryo (in terms of chromosomal number) and strongly advocate throughout clinicians and patient advocate groups for transferring just one (1) embryo to protect the health of mother and the baby. Suleman’s case nonetheless underscores the fact that reproductive medicine remains a lightning rod for various controversies, and all the physicians and researchers working in the field must be careful stewards of their work (Rosenthal, 2010).

With advancements in embryo development inside the laboratory, the late 1990s were highly notable with Gardner and Schoolcraft's lab in Australia responsible for a lot of extended embryo culture work by improved understanding of the nutritional needs of developing embryos and to culture them to the blastocyst stage which is five (5) to six (6) days after fertilization.

A blastocyst is much more advanced than a three-day embryo, much easier to screen for genetic health, and much more likely to implant after transfer. This has made it possible to offer single embryo transfer procedure to many patients, hugely reducing the risk of multiple pregnancies.

As we moved toward the late 1990s and into the new millennium, IVF evolved as the principal infertility treatment method, getting better and better each year. Pre-implantation biopsy of embryos was first developed in the 1990s and has seen widespread adoption in recent years. This has allowed us to carefully select embryos for transfer, avoiding birth defects, miscarriages, and multiple pregnancies in the process. Genetic testing is still an extremely active area of research in field of reproductive medicine and where most of the advances are being made in 2020s in reproductive medicine (Reimundo 2021).

Pre-implantation Genetic Testing (PGT) is divided in three types;

a) PGT-A (Aneuploidy).

b) PGT-M (Monogenic Disorders or single-gene affected).

c) PGT-SR (Chromosomal structural rearrangements affecting recombination and future offspring).

2.1.15.1 Pre-Implantation Genetic Testing PGT-A (Aneuploidy)

PGT-A (Pre-implantation genetic testing) – Aneuploidy, also known as aneuploidy testing, is utilized to examine the chromosomal structure of the embryos. It can quantitatively and definitively inform if an embryo contains an excess or a shortage of chromosomes.

A large number of miscarriages are attributed to chromosomal abnormalities, making ‘PGT-A (Pre-implantation genetic testing – aneuploidy) a valuable tool for women who have experienced multiple miscarriages without an explanation. It can also lower the risk of having a child with a significant genetic disorder.

2.1.15.2 Pre-Implantation Genetic Testing PGT-M (Monogenic)

Pre-implantation genetic testing for monogenic, also known as PGT-SR, Individuals with a history of passing down severe or potentially fatal genetic conditions can now identify genetic abnormalities in embryos. This is done through a procedure called embryo biopsy, which provides the same kind of diagnostic information as current methods used in fetal genetic testing, such as NIPT (non-invasive prenatal testing), amniocentesis, and CVS (Chorionic villus sampling).

2.1.15.3 Pre-Implantation Genetic Testing PGT-SR (Structural Rearrangement)

Pre-implantation genetic testing for structural chromosomal rearrangements, also known as PGT-SR, is a genetic examination carried out on embryos developed through in vitro fertilization (IVF) to identify any structural changes in chromosomes, which are often caused by balanced translocations and inversions.

These structural changes in chromosomes can be passed down from parents or may happen randomly (de novo) It's believed that about 1 in every 500 individuals have a balanced reciprocal translocation, and many of them are not even aware of this genetic condition, leading to a normal and healthy life.

However, individuals usually discover they are carriers when they attempt to conceive. Individuals who carry these balanced rearrangements can either pass on the same genetic change or may produce embryos with unbalanced chromosomal rearrangements.

This can lead to unsuccessful pregnancies or result in the birth of a child with genetic disorders. PGT-SR can enhance the likelihood of a successful pregnancy by screening embryos for chromosomal rearrangements, ensuring that only those with the correct chromosomal makeup are chosen for implantation (Marin, 2021).

2.1.16 Non-Invasive Pre-Implantation Genetic Testing (niPGT)

The latest finding of DNA in the Blastocoel and the Spend culture media (SCM) has sparked a renewed interest in the potential for a less invasive form of PGT. A possible advantage mentioned is the avoidance of the high costs associated with the gold standard Trophectoderm biopsy technique which is invasive.

The concordance of nucleic acid testing (niPGT) strategies in terms of the percentage of samples that provide usable data and the consistency of genetic outcomes compared to those from whole embryos or biopsy samples, has shown a broad range in the literature. The DNA discovered in BF and SCM is present in lower amounts and is of lesser quality, creating technical difficulties for genetic analysis.

It remains uncertain which laboratory techniques are best suited for analyzing extra-embryonic DNA. There is a lack of consensus on the most effective approach for niPGT, and doubts about the accuracy and practical value of the data lead to the recommendation that PGT based on blastocoel aspiration or SCM analysis should only be performed within the guidelines and framework of pre-clinical research and carefully planned clinical trials.

Essentially, for precise data analysis and to prevent misdiagnoses in the clinical settings, it is crucial to establish the source of the extra-embryonic DNA and to explore the reasons for the discrepancies between the findings and those derived from the biopsy tissue (Tomic, 2022).

2.1.17 Assisted hatching (laser assisted hatching)

The early stage of the embryo, known as the zygote, is enveloped in a dense protective layer of unique proteins, referred to as the zona pellucida. In order to the embryo to attach to the uterus, it must overcome this barrier by "hatching" or breaking free from the zona pellucida.

It's a widely held belief that the process of assisted hatching, which involves the use of chemicals, lasers, or other methods to loosen or open the zona pellucida, facilitates this hatching process. The emergence of the blastocyst from its protective shell is a crucial phase in the series of physiological occurrences that lead to the attachment of the embryo to the uterine wall.

A lack of proper hatching, potentially due to defects in either the blastocyst or the zona pellucida, could be one of the obstacles affecting fertility in humans. Assisted hatching is a technique designed to facilitate the embryo's ability to "hatch," or emerge from the delicate membrane that encapsulates it, named the zona pellucida.

This hatching process is essential for the embryo's ability to attach to the uterine wall. In the case of embryos from individuals with unfavorable prognoses, a failure to hatch independently could lead to a reduction in their chances of implantation and successful pregnancy.

During the assisted hatching process, an embryologist meticulously creates a hole or modifies the zona pellucida prior to transfer. Assisted hatching (AH) also known as laser assisted hatching, involves artificial thinning or breaching of the zona pellucida

layers which home the embryo and has been proposed as one technique to improve implantation rates after in-vitro fertilization (IVF) (Hammadeh, 2011).

2.1.18 Time Lapse Microscopy

A recent innovation in the field of fertility treatments is the use of time-lapse microscopy and AI evaluation of embryo growth in a specially designed incubator. This technology captures photos of embryos as they develop, reducing the need to extract them from the incubator repeatedly, thereby minimizing their exposure to potential errors in handling or airborne particles that might harm them.

A single embryo is photographed every five minutes, and these images are compiled into a time-lapse video, allowing the embryologist to observe and track the embryo's growth and division continuously, all within the controlled conditions of the incubator. Utilizing sophisticated algorithms and AI, researchers are now able to identify patterns in embryo development.

This research suggests that specific timings of cell divisions can be indicative of the embryo's viability, aiding in the selection of the healthiest and most suitable embryos for transfer, which ultimately results in improved patient outcomes (Kandari, 2019).

2.1.19 Artificial Intelligence in IVF

In India and around the world, infertility treatments have hit a plateau. The rate of success has stayed the same over the last ten years, ranging from 30-50%, depending on factors like the availability of donor eggs or sperm, the age of the couple, and issues like laparoscopic surgery for gynecological problems and the success of sperm retrieval from low-quality samples.

However, the use of both general and specific treatments, such as PGT (pre-implantation genetic testing) for known infertility issues, has led to better outcomes for a specific group of patients with complex infertility or those patients with additional health conditions like single gene disorders, genetic abnormalities, or chromosomal issues.

Nowadays, the vast amount of information and records in patient files and medical records is attracting tech companies to find ways to use this data to improve patient care and outcomes.

Beyond just managing data, there's also the idea that using artificial intelligence in various parts of the in vitro fertilization (IVF) process, from choosing the best eggs and sperm to creating a personalized IVF treatment plan, could ultimately benefit those undergoing fertility treatments.

However, like any new technology, the use of artificial intelligence in IVF also raises concerns and potential risks. Discussing the situation in India regarding the role of technology and artificial intelligence in fertility, we find ourselves in a period where the fertility treatment sector is still in its early stages of development and has recently

encountered the implementation of a New ART Bill and its associated regulations that outline the requirements for staff and their qualifications.

While there may be some immediate challenges, the ultimate advantage of having such legislation is that it paves the way for the industry to expand in a more organized and consistent manner. Following the introduction of the ART Bill, many experts remain hopeful about the compound annual growth rate (CAGR) of infertility and related services in India, including the adoption of technological advancements.

This optimism is fueled by several factors, such as the emergence of a growing market, the rising income levels of both rural and urban middle and upper-middle classes, an improvement in their creditworthiness, and an increase in the average age of marriage among the educated population, which results in a greater demand and uptake of infertility services.

Moreover, the combination of India being the leading sector for the development of Information Technology products and a burgeoning sector for Artificial Intelligence products, along with the potential of homegrown projects, makes the domestic market for these technologies highly attractive and worthy of attention and observation.

At present, the majority of technological advancements are fueled by products provided by companies that rely on 'black box' or secret algorithms, often incorporating artificial intelligence. There are several challenges and widespread worries regarding data protection and ownership, along with the significant expense involved in setting up the product.

2.1.20 Future Direction and Controversies

The field of fertility treatments is constantly evolving, with scientists always on the lookout for innovative methods to assist couples in conceiving. Each breakthrough presents new possibilities for a broader group of people and instills renewed optimism in addressing fertility issues that were once deemed insurmountable.

The potential of pre-implantation genetic testing, which is currently accessible only to couples going through in vitro fertilization (IVF) treatments, could become much more widespread in the near future, thanks to a device discovered on a cattle ranch that ignited a revolutionary concept in fertility treatment.

Incorporating Pre-implantation genetic testing (PGT) into natural pregnancies, such as through uterine lavage in the process of ovulation induction enables women to sidestep the heart-wrenching choice of whether to end a pregnancy upon receiving PGT results showing a genetic flaw.

Presently, scientists worldwide are on a path that started ages ago. The limits of what can be achieved with IVF and infertility treatments are continually being pushed. The goal remains unchanged: to provide every individual who aspires to be a parent with the chance to eventually embrace their healthy, joyful child.

2.2 Total Cost Optimization Strategies in Healthcare

The global as well as Indian healthcare industry is transitioning rapidly from just a volume-based model to a value-based one. Consumers are increasingly demanding improved healthcare quality delivery, placing healthcare providers and insurers under a positive pressure to deliver better outcomes including improved communication and counseling as well as discussion of possible side effects as well as deliverance of service and various treatment options available to the patients. The scarcity of primary care physicians and nurses means that overburdened professionals become even more productive and efficient.

Today cost dynamics of healthcare have changed due to increased life expectancy, prevalence of chronic illnesses and infectious diseases, and preventive medicine practices. Additionally, new players and alternative healthcare delivery methods are adding complexity and competition to the industry.

The compelling need to achieve more with fewer resources emphasizes the importance of a new approach in healthcare operations which is optimizing healthcare delivery and payment processes. When critical healthcare decisions are based on intuition or rudimentary tools, the outcomes may be suboptimal and compromise overall process and patient safety.

In this modern age of big data, any successful transformation approach must be driven by real-time data enabling evidence-based and transparent decision-making. This is where technologies like decision optimization are to be implemented, facilitating a more evidence-based and transparent approach to decision-making.

As health care administrators look to meet the challenges of an older patient group, increased regulation, decreased budgets and global uncertainties are driving more data based robust decision making to allow for enduring the ups and downs of an evolving healthcare sector (Pan, 2019).

In the case of Fertility practice, the hospitals with geographically distributed facilities operating on hubs and spoke models in Fertility Centers face a unique challenge of intra-hospital patient transport. With the ART bill now creating further issues in disallowing gametes to be moved from one location to another without national approval, the coordination of hub and spoke centers is becoming a severe logistical challenge. This can spell disaster for patients and caregivers.

Healthcare systems can take control over operating expenses. However, simplistic and crude approaches like looking at a Profit and Loss statement to cut corners may do more harm than good. Caution dictates from previous examples in healthcare history that just cutting high paying staff or delaying required healthcare equipment, overworking employees and not paying vendors on time for supplies can highly hinder a hospital's ability to deliver on their outcomes and eventually leads to reduced revenue and patient satisfaction.

Many hospitals are now using expensive tools to help planning and dispatching working on optimization models to ever-changing hospital and transport data, which help hospital administrators manage and execute hundreds of daily requests in real time basis. Thus, on time punctuality KPIs (key performance indicators) are now playing a large role in healthcare delivery (Pan, 2019; Kuttappa, 2020).

Another healthcare example is radiation therapy. Now, mathematical optimization to design radiation treatment plans are commonplace, enabling clinicians to precisely target which beams turn on, when and for how long to deliver an optimal dose for each patient.

Psychiatry service offers another example, where using mathematical model cost optimization, has resulted in 8 to 10 % (percent) increase in referrals per year and reducing waiting time for psychiatric patients whose health may suffer from any further delay in care delivery.

Further in the hospital industry of 2020s, in the business and planning side there is increased use of prescriptive analytics for accurate staffing levels, inventory management and ambulatory care services (Kuttappa, 2020).

These examples demonstrate how health care organizations globally are improving quality of care, cutting costs and increasing transparency in all functional areas.

With small businesses and organization taking up outsourced finance, accounting, training and even HR management, hospitals can benefit from standardization using vendors for basic business functions like IT, HR, foodservice, labs and pharmacies and have cost reduction to reduce overhead while their revenue can be used for re-investment in new advance machine which are technology superior, experienced clinicians and other critical functions in the hospital which may directly help the organization improve the healthcare delivery with improved care to the patients.

2.2.1 Clinical Engineering

Looking at a hospital's clinical engineering contracts is the first area for cost reduction strategy. There are multitudes of contracts with maintenance vendors for equipment used to diagnose, treat and monitor patients at various levels and intervals. In the case of Fertility hospitals this includes embryology and andrology laboratory equipment which are highly priced and expensive to maintain.

Reducing these contracts into a single contract with one clinical engineering provider can sometimes save lakhs in revenue. If that is not possible, renegotiation, buying new equipment where contracts are more expensive to save future costs are great ways to target cost optimization.

It is essential during cost optimization to look at the big picture first. The cost optimization plan should be expanded to include divisions not directly related to treating patients and finding sustainable ways to reduce overall overheads.

For example, let's discuss the food service. Standardization occurs in the production of the food, following menu costs, recipes, and waste reduction. Contracts should dictate financial and quality KPIs. Outsourcing in this category results in 11% savings across the system in hospital cost savings.

Apart from that, the health infection committee and environmental services outsourcing can save around 5% costs as well as bring standardization in mundane tedious tasks (Kutteh, 2020).

2.2.2 Workflow Management

Workflow and personnel can be one of the most unstandardized and difficult areas in a hospital. Patient and personnel workflow can unveil opportunities for cost reduction. Patient movement efficiency can decrease costs and enhance care.

Chauffeured patients are happier and are more efficient for the hospital. This streamlines operations and reduces bottlenecks. Many times, using technology and strategized personnel intervention hospitals can minimize delays, reduce wait times, improve staffing and increase bed occupancy rates.

Apart from workflow, the workforce itself can be a source of major stress and worry if not handled with strategy. Cost optimization does not directly mean workforce reduction. Alternative strategies like investing in staff training, more time offs with multiple cross trained staff, reducing overtime, improving employee retention initiatives, and implementing recognition programs. These measures reduce costs without compromising the quality of patient care or increasing staffing issues.

2.2.3 Train and Develop

Statistics inform us that about two thirds of employees with lack of training leave their workplace for a better place to work. Adequate job-related training and development is an incentive for employees to be motivated to stay and it reduces long-term costs for the organization.

Furthermore, a recent national survey found that 70-90% of respondents said additional training and development boosted their confidence in their employer and helped them remain in their position. The newer generation, also called millennials for people born in the 2000s, also shared the need for higher motivation and interest in keeping the job which provided with continuous growth opportunities.

2.2.4 Employee Retention and Workforce Management

A focus on reducing turnover and retaining staff is a cost-reduction strategy that healthcare systems can borrow from other industries. It is expensive and time-consuming to devote resources to continually recruiting new staff. Employee satisfaction and a positive work environment & culture are fundamental ways to combat turnover and reduce costs.

Ensure that healthcare workers are getting the right amount of break time or time off between shifts. You can also help prevent burnout by monitoring things like overtime and man-hours required to do a particular task.& providing appropriate time & people for the task.

To get a sense of where the hospital can improve the employee experience, consider conducting an employee engagement survey either by self (can have biased results as anonymity is difficult to maintain & employees feel conscious that company can use the feedback against them personally) or preferably by a 3rd (third) party professional company having expertise in the same..

If you start working towards these goals, you will save money in the long run by retaining your staff. Healthcare cost reduction strategies should be about more than spending cuts. Public recognition and appreciation of your hospital teams and staff is another way to reduce costs and improve retention. Celebrating employees for a job well done on a consistent basis has a measurable impact on employee engagement and retention (Kutteh, 2020).

It is difficult, but not impossible, to implement cost reduction strategies that streamline processes while maintaining high-quality patient care. To reduce costs in your health system, review current contracts and consider outsourcing services like catering, clinical engineering and environmental services.

Look for ways to enhance the work experience of your employees through training and recognition schemes. Support the creation of an environment that is conducive to staff retention. Finally, to ensure that your hospital maximizes throughput and minimizes avoidable readmissions, review key areas such as patient flow and malnutrition coding (Kutteh, 2020; Pan, 2019).

2.2.5 Directions of Cost Optimization for fertility units in India

A major cost driver in fertility centers is the cost of drugs used in fertility treatments. The cost of drugs accounted for about 60% of the final cost of in vitro fertilization (IVF) treatment in India; hence use of biosimilars, generic drugs and bulk purchases can significantly reduce the cost of drugs in fertility treatments which in turn can reduce the overall cost.

Another recommendation is the use of a shared-risk model, where the cost of treatment is shared between the fertility center and the patient. Under this model, the fertility center would offer multiple treatment cycles at a fixed cost, and if the patient fails to conceive after a certain number of cycles, the patient will receive a partial refund. This model would incentivize fertility centers to provide the most effective treatments and reduce the financial burden on patients.

In addition to drug costs, the cost of equipment and infrastructure is also a significant cost driver in fertility centers. Outsourcing laboratory services and sharing equipment among multiple centers can significantly reduce the cost of fertility treatments. Use of telemedicine is also another way to reduce the need for patients to travel long distances for consultations.

Use of data analytics can help fertility centers optimize their operations and reduce costs. Data analytics can help identify inefficiencies in the treatment process and improve patient outcomes while reducing costs.

In conclusion, cost optimization of fertility centers in India is a crucial topic of research, given the high cost of fertility treatments and the increasing demand for these services. The existing research suggests that cost optimization can be achieved through the use of generic drugs, shared-risk models, outsourcing laboratory services, sharing equipment, telemedicine, and data analytics. These strategies can help reduce costs and improve the accessibility of fertility treatments for economically challenged couples in India (Oudshoorn, 2017; Van Tilborg, 2017a; Van Tilborg, 2017b).

2.3 Current Fertility Market in India

The current Fertility market in India is poised to grow at a CAGR (Compounded annual growth rate) of 18% as compared to global average growth rate of just 5.5%.

Currently the Fertility market is valued at about $793 million and estimated to be valued at $3.7 billion by 2030. The growth in the fertility market can be attributed to several factors some of are mentioned below:

a) Delay in conception due to women pursuing for higher education, focus on career and financial stability.
b) Increased disposable income.
c) Planning for conception at advance age thus fertility treatment to reduce time to pregnancy.
d) Better awareness & availability of information.
e) Rapid increase of IVF fertility clinics & hospitals across India increasing access to care.
f) Availability of advance machinery, equipment, medicine, media & consumables.
g) Better success rate in IVF treatment than in the past.
h) Increased availability of gamete donors (Oocyte/egg & sperm).
i) Availability of better & advanced diagnostic testing.

In India the Female fertility treatment has a much higher share in the overall segment and one of the major factors is most fertility centers in India do not have an uro-andrologist (male infertility specialist) A lot of males are diagnosed with Zero sperm count which would require surgical extraction and a Urologist surgeon is required to perform this surgery.

The major share of the fertility market is dominated by the major metropolitan, tier 1 & tier 2 cities. In rural areas the access to care is almost negligible, people intending to get the fertility treatment need to travel to the nearest city where the fertility services are available.

India is fast becoming a destination for medical tourism in fertility treatment, fertility treatment cost in India ranges from $1200 to $2500 as compared to $6000 to $15000 in UK & $12000 to $30000 in US, A lot of medical tourists are travelling from across the globe for fertility treatment.

The per capita income in India is approximately $2000 thus the cost of fertility treatment in India is still out of reach of most of the general public (Chambers, 2009).

2.4 Summary

The Indian Government as of now does not provide any kind of cost subsidy or financial assistance for infertility treatment for the general public. Majority of fertility centers are not registered with ICMR (Indian council of Medical Research) thus the ART cycles performed by individual fertility centers are as of yet not reported exhaustively to the government or any other body (Tank, 2023).

Women with an age range of 30 to 35 even with normal BMI (Body mass Index) the total cost of diagnostic investigations and overall treatment cost were higher compared to younger age groups (Pandey, 2020).

In India generally females complete their Higher education by the age of 21 to 26 depending on field of study they choose, and typically they dedicate about 3 to 5 years to build their career and delay the decision of having a child due to various reasons, by the time they are mentally ready to conceive they cross the age of 30 years and the overall higher cost of diagnostics and treatment kicks in depleting their savings and affecting their future financial planning. Therefore, there is a need to drastically reduce the infertility treatment cost so that the low- and middle-income population can have access to infertility treatment and care.

In LMICs (Low- and middle-income countries), there is a need for intervention and guidance from a higher body like WHO (World health organization) to raise the standards of quality, improve access to infertility care and general social acceptance of infertility treatment (Chiware, 2021).

In India Infertility is still related to a lot of social stigmas thus the infertile individual / couple struggle to socially accept that they would need medical assistance for having children.

As per a market report by global market insights, a major roadblock in infertility treatment is the deterring high price of the various procedures and multiple social barriers and inappropriate infrastructure (Ugalmugle & Swain, 2020).

Health experts have suggested bringing infertility treatment under insurance cover but up till now only 3 small insurance providers are providing health insurance plans that cover infertility, but the covered amount is very low (The Mint, India, 2019).

The ART Regulation Bill 2021 has led down strict regulations related mainly to third party reproduction services in India. Third party reproduction involves use of either male or female donor gametes or gestational surrogacy involving a third person apart from the commissioning couple who shall be donating or compensating the same with financial assistance in case of donor gametes and altruistic with a person of familial ties in case of surrogacy.

The laid down sections limit the division of oocytes or sperm retrieved from the donor to be used only once in their lifetime and to only one recipient couple. This change can significantly impact on the cost of infertility treatment and increase the same from an average Rs. 1,50,000/- to up to Rs. 3,00,000/-. The entire Indian IVF fraternity is now faced with the daunting challenge of keeping the infertility treatment costs down without compromising on the average success rate of 40% worldwide (Tank, 2023).

Let us present some facts and figures from the other point of view of Population explosion in India which has been a base criticism leveled against development of ART Services in India from economic pundits to self-proclaimed Maharishis or Sadhgurus in India to level the field of enquiry. It is postulated that India is a developing country with a total population of 1.4 billion people which is roughly 16.7% of world population.

As per Indbiz Economic Diplomacy Division news article (2021), India ranks 2nd (second) in terms of world population and with an average age of just 29, is one of the youngest populations globally. This explains the very little or no intervention or help from the government for the Infertility treatment in India. However, please note, this means nothing to the aspiring couple who are biologically and rightfully seeking to have their own child.

Biological imperative cannot be superseded by claiming betterment of society when reproductive freedom is quintessentially one of the pillars of freedoms available to an individual. The lack of services in the country will just allow an industry to crop up in the nearby countries and drive up the cost per cycle for Indian patients.

Critics would again point out that a population control bill 2019 was a proposed bill introduced by the government in Rajya Sabha (yet to be passed and adopted) with a two (2) -child policy for each couple and various penal clauses to demotivate the people from having more than 2 children.

Individual states like Uttar-Pradesh have already taken a lead and have announced that couples with more than two (2) children will not be able to take the various

government benefits including being not eligible for state government jobs in the state of Uttar-Pradesh India.

Indian government has been running family planning programs since 1952 to control the population burst in India, a variety of programs have been introduced like "Mission Pariwar vikas" by Government of India, 2017 from usage and promotion of contraceptive and other birth control measures with various subsidy and free assistance for the same, and providing various information and assistance to couples and various methods and services available (Government of India, 2016; Government of India, 2017).

And as we commend the benefits of these programs in educating people in regards to their reproductive health and family planning, reproductive and family planning is at the basis the core principle guiding the formation of Reproductive Health and Fertility Centers in India wherein Fertility is not the end-all service and is one of the services provided under the spectrum of gynecological, andrological and reproductive health (Tank, 2023).

Another point raised is the high number of abandoned children in India and a push for the Indian government to put higher impetus to couples on child adoption vs. Assisted Reproductive Technology use. A study suggests that by addressing the 4 main causes of low Child adoption in India that are biological child desire, fear of social implications of implied illegitimacy, social ostracization and medical requirements of any genetic of special needs the child may turn up having. These can be addressed by creating awareness, change in perception and ease in law related for child adoption, these measures will increase the child adoption rate in india and hence the child aspiring couples can adopt instead of reproducing not only reducing the financial burden on

couples but also addressing the problem of India's high number of orphaned and abandoned children (Joshi, 2015).

However the actual numbers speak of a different reality. In-spite of ART (Assisted reproductive techniques) in India having a very moderate success rate; the child adoption rate in India is very low. As per UNICEF total orphan and abandoned children in India is about 30 million. Unfortunately, in-spite of low ART success rate, high cost of treatment and involvement of various other troubles and cost directly and indirectly related to Infertility treatment only less than 50% of the infertile couple considers child adoption as the last choice (Standard, 2018).

A highly alarming and concerning fact is that children conceived via in vitro fertilization (IVF) have a roughly one-third higher risk of congenital malformations than other children. IVF children have a 1.3 times higher chance of cardiac malformations while the risk is 1.4 times for musculoskeletal malformations and 1.58 times higher for genital and urinary disorders.

Further the odds of high-risk pregnancy increase with IVF. The odds of preterm birth are 1.7 times higher while that of low birth weight are 1.5 times greater in IVF singleton pregnancies. Cardiovascular system disturbances which stem from alterations are increased, although modern IVF has not shown an increase in these disorders in 2020s but previous data suggests caution and continuous follow up of the IVF born children (Reimundo, 2021).

Unfortunately due to the private nature of the healthcare practice and a lack of government mandata, the risks are less known and propagated and glossed over many

times in news or websites or by healthcare practitioners. Of course, modern Fertility procedures have been shown safe mostly for long term child health and it has been postulated that the risks may be driven rather by advanced age than the interventions themselves in skewing the results to show a higher odds ratio of being affected by the mentioned issues.

An additional issue is the incidental expenses that accompany fertility treatments, which primarily concern care of newborns. Since preterm newborns account for more than half of neonatal intensive care unit (NICU) costs, the majority of studies on the costing of this type of treatment have focused on this aspect.

Determining the cost-effectiveness of extremely preterm newborns and those nearing viability thresholds has been the main focus. The overall NICU expenditure is biased towards care of moderate and late preterm infants, despite the fact that the costs of care have an inverse connection with gestational age (GA) and that the lifetime medical costs of the severe preterm might reach up to Rs 3 Crores (Reimundo, 2021).

For premature infants with high viability, neonatal intensive care cost can range from costing Rs 10000/- or about $1200 for a term newborn and Rs 15,00,000/- or about $ 19000 for the severely premature. NICU care is relatively cheaper in low- and moderate-income global regions like India where NICU resources are scarce, because of a patient profile that includes more term and preterm patients with higher Gestational age which require less intensive care. Low gestational age preterm generally has very high mortality in these regions and social acceptance of avoiding medical expenditure under such scenarios is also observed.

If we consider overall medical treatment history, infertility treatment is relatively new in the timeline, with the first IVF baby born in 1978 and till date the overall benchmark success rate for infertility treatment is 40%. The industry segment is still evolving and with the fast-changing overall fertility health of the people due to various factors like sedentary lifestyle, junk food, genetics and many more, the problem is going to get more complicated than ever before.

Lack of sufficient published data on infertility treatment cost and measures to bring down the cost is a major hurdle. At present there are just a handful of Indian manufacturing companies making very few IVF lab consumables and Medicines and some of these products lack proper certification or the quality/performance of the product is not at par with the foreign tested brands.

With some of the major foreign manufacturing brands in acquisition spree in India, the cost of laboratory consumables would overall increase due to an oligopoly competition in the infertility industry giving little to no incentive for controlling consumables cost, affecting the overall cost of infertility treatment.

With the Total fertility rate of India declining contributed by various factors out of which one of the major factors is cost, currently there is very low penetration in the small towns and villages of India.

Government focus on infertility treatment is missing and with the recent ART Regulation Bill 2022 it is crystal clear that the infertility industry is not the preferred medical segment for the government and no help in form of subsidy or cost optimization can be expected in near future (Tank, 2023).

Thus there is a greater need to identify the most feasible steps and methods by which the Infertility treatment cost can be reduced, and by compiling these methods and steps to develop a cost optimization measures which can be later converted to a module by which the Infertility treatment cost can be reduced, this cost optimization module can be converted to a software and powering the same with Machine learning, a new business opportunity can be created which can cater to all small and medium fertility clinics across rural India. This module can also be catered to big corporate fertility chain hospitals for cost optimization, quality control and standardization, which can be easily replicated across India.

CHAPTER III:

METHODOLOGY

3.1 Overview of the Research Problem

The ART (Assisted reproductive techniques) Regulation Bill 2022 has recently been passed by the government and implementation has begun. Furthermore, the bill regulations and guidelines are not in sync with the current industry practices and thus lack practicality currently facing major protests from the infertility practicing doctors, clinics and companies. These regulations and guidelines will adversely change the way the infertility industry functions, affecting the overall infertility treatment cost and the brunt must be borne by the child aspiring couples who need treatment.

Lack of sufficient published data on infertility treatment cost and measures to bring down the cost is a major hurdle. At present there are just a handful of Indian manufacturing companies making very few IVF lab consumables and Medicines and some of these products lack proper certification and the quality/performance of the product is not at par with foreign brands.

With some of the major foreign manufacturing brands in acquisition spree in India, the cost of laboratory consumables would increase due to an oligopoly in the infertility industry giving little to no incentive for controlling consumables cost beyond the limited competitive circles, affecting the overall cost of infertility treatment.

With the Total fertility rate of India declining contributed by various factors out of which one of the major factors is cost, currently there is very low penetration in the

small towns and villages of India. This lacuna has been addressed by for profit, funding driven Indian and overseas corporate chains who have initiated a spree of capital investments in setting fully equipped or hub and spoke modeled Fertility hospitals focusing on Tier II cities in India. Of course, the model is semi successful in addressing the problem of access but does nothing to address fiscal constraints that prevent couples from visiting these hospitals. Overall costs remain formidable for the patients and even for the corporate entities involved (Ugalmugle, 2020).

There are small to medium Fertility hospitals catering to patients in Tier I -III cities already and many have taken up the mantle of entrepreneurship in the last three decades in Fertility medicine in India. Almost 70% of the market share of Fertility treatment still belongs to the regionally strong clinicians and small doctor groups in the country (Guest Financial express, 2021).

Here eventually it is the Clinician Entrepreneur who runs the setup as an individual owner or a partner. However, these small units provide exemplary personal service. Lack a corporate fiscal team or an effective operations team that evaluates and runs cost optimization and rationalization at regular intervals for them. These are the bulk of fertility providers in India and our research is focused on them and for them.

So below are the problem questions that our research shall be answering;

Q1) What are the key factors contributing to Cost of Fertility/IVF treatment in India and how to make IVF treatment more affordable?

Q2) What cost optimization methods will have the largest impact and which are feasible for implementation by ranking them for IVF Centers.

3.2 Research Methods Selection

Out of the different methodologies to choose from, A Quantitative method which is a research survey was the most appropriate. A detailed survey questionnaire will be drafted since the questions will be related to Clinical Protocols & embryology lab protocols for knowing the cost implications with various permutations & combinations of the treatment protocols.

Hence, only the Clinical IVF Infertility specialist or Clinical Embryologist who are the IVF center owners and have access or knowledge of the overall & detailed cost parameters are suitable to be the participants for the Survey.

Once the survey is completed the inputs will be collated & analyzed to understand the cost centers & different cost optimization interventions that the IVF hospitals are undertaking.

Since the whole survey is relating to internal cost which is the most sensitive data which any of the company will have reservations in sharing making thus making this survey completion the most challenging, also the target participants are the Owners of the IVF hospital or part of the Top management hence getting their time to get the survey filled would be very challenging.

3.3 Research Purpose and Questions

Our research purpose is to provide optimization methods utilized in the Fertility Industry by stakeholders and to create a narrative review of comparing these methods with other countries or other healthcare domains in India or abroad to give a holistic view of where our Industry is currently operating from and whether these attitudes and methods are evidence driven and appropriate. IVF is known to be expensive and limited in access in India.

The proposed research plan is to run a comprehensive questionnaire across the medical fraternity of IVF industry to understand their cost reduction methods and current constraints. This questionnaire shall be run for the fraternity via online forums to make a note of their constraints: financial, clinical and otherwise to understand a list of issues faced by them.

Through this survey research we seek to identify key factors contributing to the cost on IVF for patients from the perspective of cost incurred by Fertility centers through consumables, healthcare staff, keeping inventory, losses due to unavoidable circumstances on a ground level by surveying the key stakeholders in an IVF hospital and create the survey through multiple questions of cost cutting ,optimization methods, clinical usage of high cost procedures and interventions that are most likely used.

These shall be ranked by survey respondents to get an overview of how current IVF practitioners are dealing with the cost factor of providing IVF and what interventions they are choosing and in what order to IVF more affordable. We have further with a panel of experts created a mock scenario for each question ask to determine by financial

calculations to determine the scenario-based savings or losses due to interventions chosen.

The complete analysis of survey findings with mock scenario testing is done to evaluate the feasibility and rationality of current practices on the ground level. This research is attempting to create a complete survey data of cost saving practices compared to mock scenario testing to identify the interventions with highest cost implications and attempts to provide robust data analysis to compare the same with current provider responses in order to distill the path towards creating improved access to care and market penetration in the IVF industry for healthcare providers in India.

Q1) What are the key factors contributing to Cost of Fertility/IVF treatment in India and how to make IVF treatment more affordable?

Q2) What cost optimization methods will have the largest impact and which are feasible for implementation by ranking them for IVF Centers.

Survey results shall be tabulated and a literature survey of current cost optimization methods by users as well as via published literature will be made and these will be put in the workflow of the current IVF setup to evaluate and rank each of them, based on user defined feasibility and ease of use.

3.4 Research Design

To conduct this study, the most suitable method would be survey research. A comprehensive online survey will be created to reach a representative piece of the population of infertility specialists and stakeholders to allow for a diverse respondent group. A cross-sectional survey shall be conducted. Mixed Model Open and Closed Type and a targetted questionnaire will be developed. The following statistical scales shall be used for response collection;

1) Nominal Scale - Responses requiring a selection of specific item or vendor or product. Example – What gonadotropin type do you use for self-cycles of ART (IVF /ICSI).

a) Recombinant FSH.

b) Human Menopausal Gonadotropin (hMG).

2) Ordinal/ Likert Scale – Responses requiring likeliness scale. Example - I will shift to minimal stimulation for IVF to reduce overall costs.

   Strongly Disagree ….. Strongly Agree

3) Interval Scale – Responses requiring a certain range of value attached. Example - What is the cost of IVF Cycle in your center?

   <50000

   50001 – 100000

   100001 – 150000

   150001 – 200000

   200001 – 250000

   >250001

3.5 Population and Sample

Since the number of Infertility clinics/hospitals with full-fledged IVF laboratory In India is just about 1750+ and very randomly scattered across India, a convenience sampling method would be more appropriate (Ernst and Young, 2015).

As per a population sampling of 10000 and online Qualtrics sample calculation tool, for a Confidence Interval of 90% with 10% Margin of error, a sample size of 68 is calculated for sample survey (Qualtrics, 2023).

3.6 Participant Selection

A reference-based system will be used (snowball sampling) for conducting detailed interviews and online surveys shall be used to reach a larger number of sample respondents.

3.7 Instrumentation

For the Study a detailed questionnaire will be prepared and shared with infertility clinics/ hospitals across India via contact data from the fertility societies. Data from the survey and literature analysis will be combined to address the research problem. Survey research is defined as "the collection of information from a sample of individuals through their responses to questions" (Ponto, 2015).

Survey research has long been utilized as a means of gathering information from individuals and groups. The methods employed allow for flexibility in participant recruitment, data collection, different instruments and tools used . Survey research can use qualitative or quantitative strategies, example is questionnaires with numerical or libert ratings, qualitative close ended or open-ended questions, or a combination known as mixed methods. Surveys are excellent at evaluating human behavious and hence these tools are used commonly in social and psychological research.

Range of survey research methods is vast, from simple inquiries posed to individuals on the street to gather insights into their behaviors and preferences, to more rigorous studies employing multiple reliable and valid instruments. Examples of less rigorous surveys include marketing surveys aimed at understanding consumer patterns and public opinion polls related to political matters.

Historically survey science has emphasized collecting data from large populations. Objective is to quickly gather information that described the characteristics of a significant sample of individuals of interest. Census surveys for example are a great

way to demonstrate this where large dataset is generated by capturing demographic and personal information.

Large consumer feedback surveys, are also examples of this approach. They are sought to provide a comprehensive understanding of the demographic makeup of individuals or gather opinions to inform programs or products targeted at specific populations or groups.

Sampling strategies play a central role in survey research, and the goal is obtaining a representative sample of the population of interest. We cannot practically sample the entire population so using a subset or sample necessary to estimate population responses is the central idea behind survey science. Increasing the size of the random sample enhances the likelihood of obtaining accurate and reliable results.

3.8 Data Collection Procedures

In this Survey, as per feasibility and to improve response rate and avoid higher than 20% non-response rate, a questionnaire with around 15 questions will be prepared and shared with infertility clinics/hospitals across India via contact data from the fertility societies.

The study will collect data through surveys, and it represents qualitative research Data will be collected through a questionnaire in a Survey format. Primary data will be collected from at least 80 IVF Centers in India in order the research produces a realistic outcome. The survey questionnaires apply heterogeneously.

The study will distribute up to 15 questions. Respondents of questionnaires are doctor entrepreneurs, fertility clinical directors, embryologists and administrators for hospitals. For the study it will expect to receive at least 70 fully completed questionnaires which will be 80 % response rate.

All responses of interviewees will be kept under strict confidentiality, and any data shared will be included in the dissertation as aggregates or ranges or narratives. No data will be shared by the researcher with other interviewees, including identities. Only exception is if the interviewees have referred to the other candidate.

After the interviews are completed, the researcher will cross reference all transcripts to identify emerging themes. These themes will then be fully explored, and commonalities will be identified. The researcher will then follow the abductive approach

and draw fitting conclusions to these phenomena. Finally, we will construct discussions using the results obtained in Survey in a narrative format.

The overall results of Survey shall be then compared to current literature for analyzing the most feasible and effective cost optimization methods which can be utilized for a cost optimized Fertility Center Model in India.

3.9 Data Analysis

Data analysis will be done using Microsoft Excel to evaluate per response statistics and overall % (percentage) of response choices of the respondents. Descriptive statistics shall be used to describe and compare the survey choice results with a mock center analysis. A narrative review of the same will be conducted to provide an eagle's eye perspective of the cost saving measures used by Fertility Centers.

3.10 Research Design Limitations

Research design is based on surveys. Objectivity of responses depends on the exposure of the stakeholders to financial information which may not be entirely accurate. There is also a "positive bias" towards selecting methods which the respondents are directly involved with.

Since the whole survey revolves around the internal cost & cost optimization interventions, which is the most sensitive information which any company would have a lot of reservations in sharing, thus getting the data would be extremely difficult.

Since the results depend on descriptive statistics and a selected mock analysis subjective bias could be introduced due to the author and the expert group of individuals selected by the author for the comparative results. The bias could sway the results towards a certain group of consensuses although real time numbers have been used to reduce the resulting bias.

As the results are based on an invited survey, it is possible that a small group of Fertility Centers with unique practices could have been excluded due to lack of survey access or inhibition of filling a public survey and sharing price & other financial sensitive information (which may help their local competitor) and may skew the results.

3.11 Conclusion

As mentioned in the literature review & various data suggests that the cost of fertlity treatment is very expensive thus out of reach for most of the normal average individual.

This is an attempt to understand the cost of the fertility treatment & various interventions by the fertility hospitals to reduce the internal cost, this survey results can act as a primary base for the follow up research which can help in reducing the cost of fertilty treatment, this advance analysis can help Government or a NGO who wishes to provide a subsidised or free treatment to the underprevelaged people who cannot afford the high treatment cost.

CHAPTER IV:

RESULTS

4.1 Research Participants summary

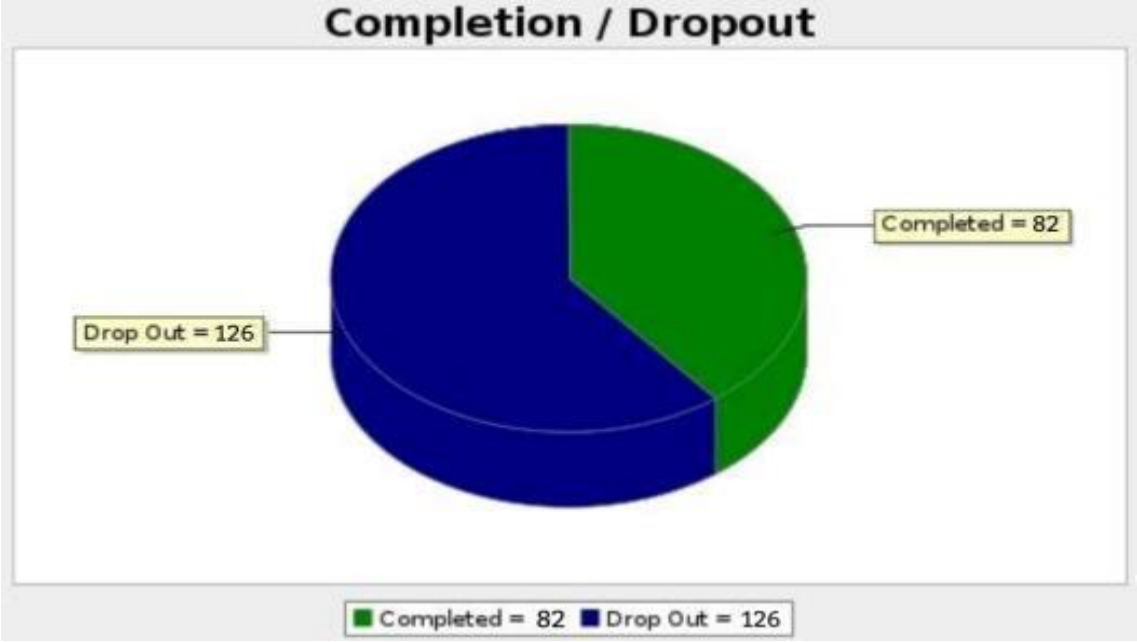


Figure 1.1.1
Pie chart showing the completion & drop out summary.

Approximately about 40% of started surveys were answered in completion. High number of dropouts may be explained by the lack of knowledge of financials of fertility treatment among the volunteer and special interest group members. Technically inclined domains like Clinical Embryology and a Consultant IVF Specialist who is not one of the founders, and hence lacking access to this information among viewers of survey might explain the same. A difference in stakeholder access to financial information could explain the higher-than-expected dropouts during survey filing.

Even the respondents who had access to the financial information might not be able to get the detailed cost bifurcation of the various procedures & treatment protocols which are being followed; this is because of the non-standard complexity of the IVF treatment procedures & protocols followed by different IVF / infertility specialist in different centers.

Table 1.1.1
Overview of survey attempt summary

Viewed	1476
Started	208
Completed	82
Completion Rate	39.42%
Dropouts (After Starting)	126
Drop Out rate (After Starting)	60.58%
Average Time to Complete Survey	29 minutes

Survey Responses were expected to have 25% approximate dropouts as per standard survey design (Bhat, 2018).

However, not only the survey is very technical in nature but also the requirement of in-depth knowledge of segregated cost parameters of each process in the IVF cycle & other allied procedures thus drastically reduces the target respondents.

It's mainly the Clinician entrepreneurs within a Fertility Unit that is regularly aware of cost implications and in some cases Clinical Embryologists who are decision

makers or part owners or Administrator/owner that are part of the fiscal rationalization process & have with in-depth knowledge of the clinical & embryological processes.

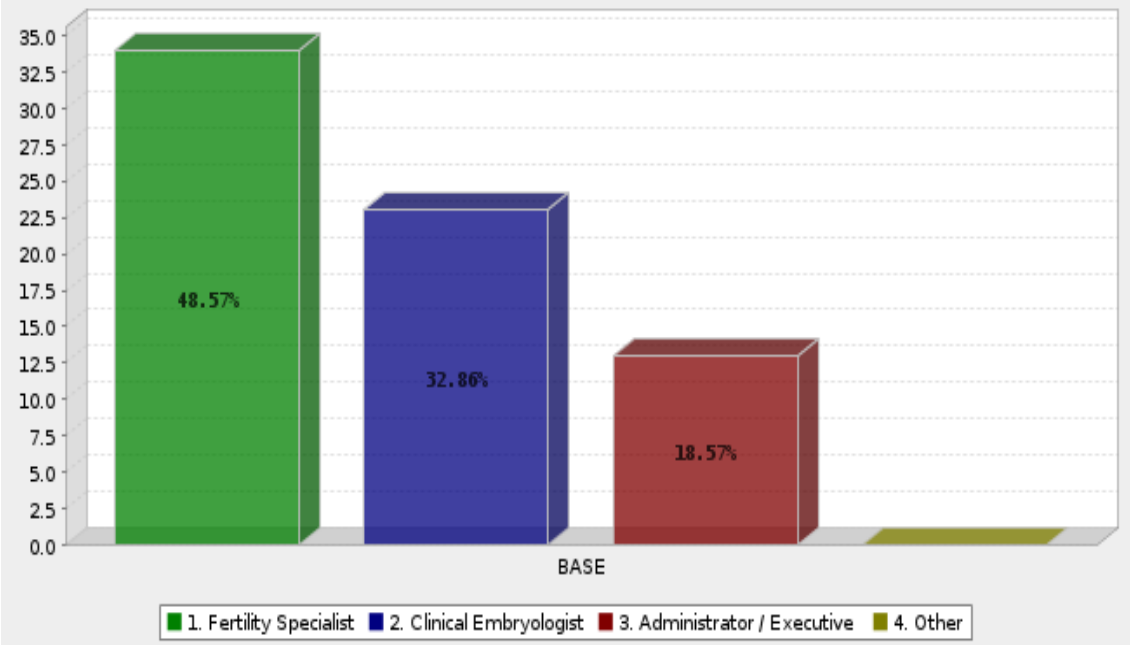


Figure 1.1.2
Percentage-wise division of respondent domains.

1) The green bar on the left represents Fertility Specialists: either Managing Directors or Sr. Consultants in the Organization running the Fertility Unit as the Center Head (responsible for the P&L profit & loss of the whole IVF unit) or having vested stake in the unit or the company.

2) The blue bar second from left represented Sr. Clinical Embryologists: either Managing Directors or Sr. Consultants in the Organization running the Fertility Unit as the Center Head (responsible for the P&L profit & loss of the whole IVF unit) or having vested stake in the unit or the company.

3) The red bar second from right represents the Owners/Administrators / Financial heads / Operations Heads with an in-depth insight in the complete financial, clinical, Embryological & other processes of Fertility treatment.

4) Others: Any other domain that is involved in Fertility Units having in-depth knowledge of the financials, clinical, embryological & other processes of IVF treatment. We had no respondents in this group.

Table 1.1.2
Survey Respondent work role-wise breakup.

Answer	**Percent (%)**	**Count(N)**
Fertility Specialist	48.57%	40
Clinical Embryologist	32.86%	27
Administrator / Executive	18.57%	15
Others	0%	0
Total	100%	82
Mean	1.70	
Confidence Interval @ 95%	[1.520 - 1.880]	
Standard Deviation	0.768	
Standard Error	0.092	

Fertility Specialists which include Doctor Entrepreneurs / Medical or Clinical Directors / Consultants.

Almost half of the respondents who completed the survey are Fertility Specialists, confirming the fact that these clinicians who are heavily invested and informed of the Fertility processes from treatment to financials are the primary decision makers in the Fertility process.

The dissemination of the survey results among this group has potential for real impact in understanding current practices in Fertility treatment in India.

Clinical Embryologists are in many cases privy to many financial realities and especially in terms of the Fertility process and form a strong stakeholder group of information providers and influencers that affect decision making in the Fertility treatment process. Their inputs and survey responses give a balance of information separate and unique from Clinical Directors or Fertility Specialists.

The remaining sizable minority is made up of Top tier management professionals who are in the role of Administrators or CEOs of the hospitals either running a Fertility unit or of a group of Fertility Centers running as a commercially driven chain. Their exposure and evaluation although in the minority is definitely slated to be better informed by the advantage of their domain expertise and both the exposure and understanding of financial requirements as well as cost saving strategy implementation as they are normally the drivers of such change once strategized.

4.2 Usage of Treatment Interventions in practice

Figure 1.2.1 shows the list of all major procedures in Fertility centers and shows the incidence of their use in practice. The higher the value the less common is the intervention in practice. It is observed that for interventions 1 to 8 as shown in the table, the interventions are common while the intervention pre-implantation genetic testing and assisted hatching are less common.

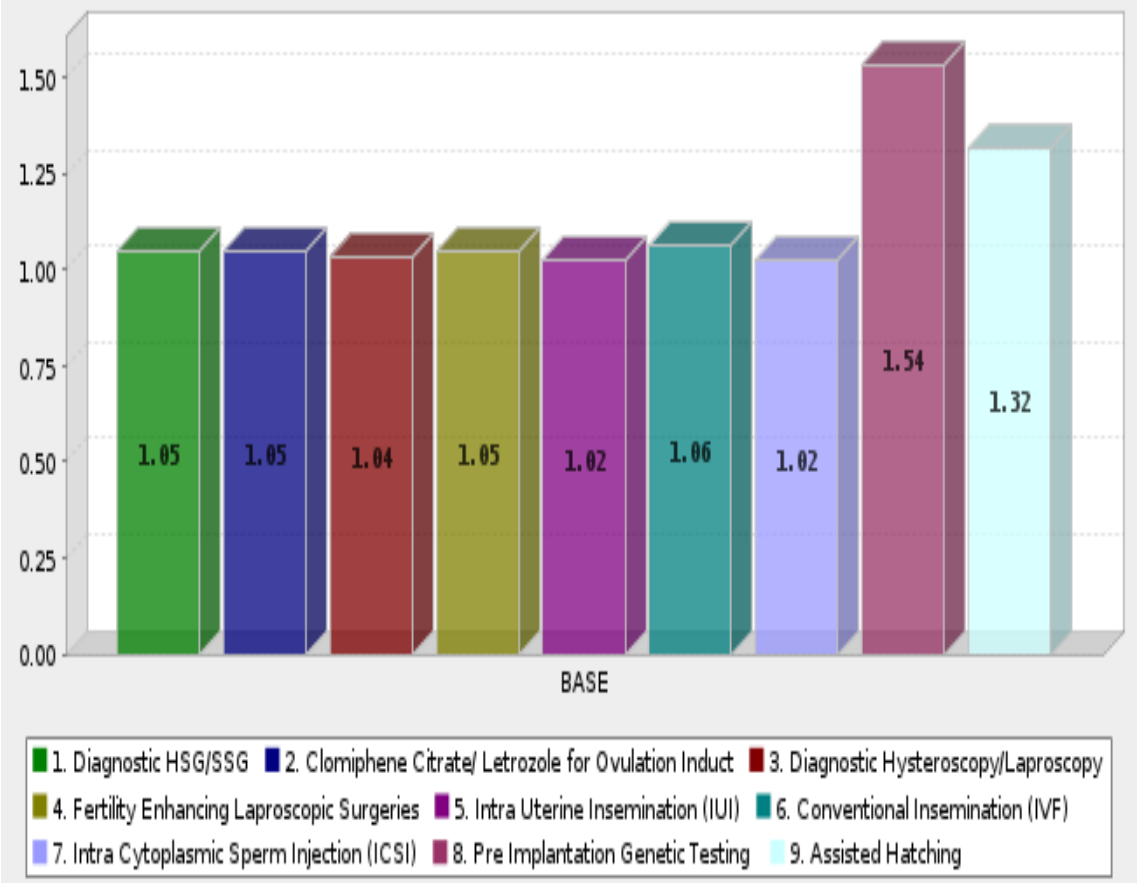


Figure 1.2.1
Matrix Score card of treatment Intervention in practice

Table 1.2.1 shows the list of all major procedures in a Fertility / IVF centers and shows the incidence of its use in practice. The higher the value the less common is the intervention in practice. It is observed that for interventions 1 to 8 as shown in the table, the interventions are common while the intervention pre-implantation genetic testing and assisted hatching are less common as for .assisted hatching an additional expense medical laser is to be purchased and for pre-implantation genetic testing the Fertility centre need to have an additional genetic license from the state government health department of the respective district.

Table 1.2.1
Matrix Score card of treatment Intervention in practice.

SN	Question	Count	Score
1.	Diagnostic HSG/SSG	82	1.049
2.	Clomiphene Citrate/ Letrozole for Ovulation Induction	82	1.049
3.	Diagnostic Hysteroscopy/Laparoscopy	82	1.037
4.	Fertility Enhancing Laparoscopic Surgeries	82	1.049
5.	Intra Uterine Insemination (IUI)	82	1.024
6.	Conventional Insemination (IVF)	82	1.061
7.	Intra Cytoplasmic Sperm Injection (ICSI)	82	1.024
8.	Pre-Implantation Genetic Testing	82	1.537
9.	Assisted Hatching	82	1.317
Average			**1.127**

Among the given interventions, which are the gamut of services provided by the fertility / IVF centre in the context of Reproductive Medicine for various infertility treatments to the patient couples aspiring for a child visiting the fertility centre for treatment, the average distribution of the services given is similar enough to allow for a comparison among respondent results in the survey.

Figure 1.2.2 shows that 95.12% of the fertility / IVF centers representative who had participated in the survey, actively practice Diagnostic HSG/SSG procedures in their respective fertility centre & offer this procedure to the patients (husband & wife) visiting to the fertility centre for treatment and the raw statistics are displayed in Table 1.2.2 in a tabular form.

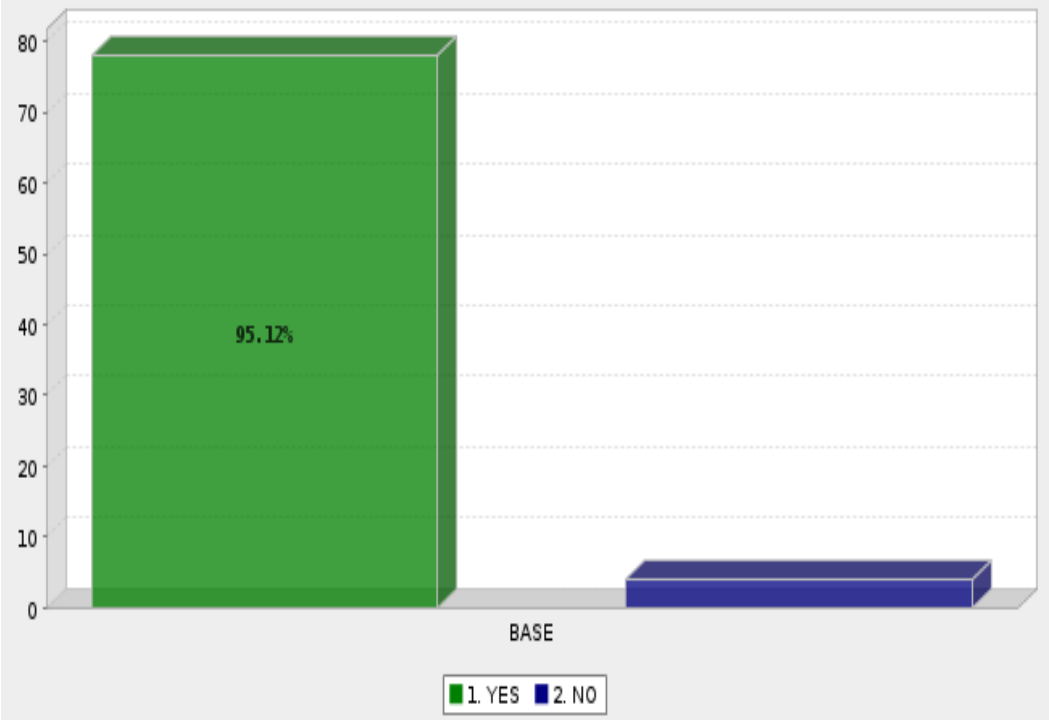


Figure 1.2.2
Percentage of Diagnostic HSG/SSG in practice.

Table 1.2.2 shows that 95% centers out of the 82 IVF centers practice Diagnostic HSG/SSG procedures in their respective ivf / fertility centres and the tabular data is displayed in the Table 1.2.2.

Table 1.2.2
Percentage of Diagnostic HSG/SSG in practice.

Answer	**Percent (%)**	**Count(N)**
YES	95%	78
NO	5%	4
Total	100%	82
Mean	1.05	
Confidence Interval @ 95%	[1.002 - 1.096]	
Standard Deviation	0.217	
Standard Error	0.024	

Figure 1.2.3 shows that 95% of centers out of the 82 IVF centers practice Use of clomiphene citrate or letrozole for ovulation induction procedures and the raw statistics are displayed in Table 1.2.3.

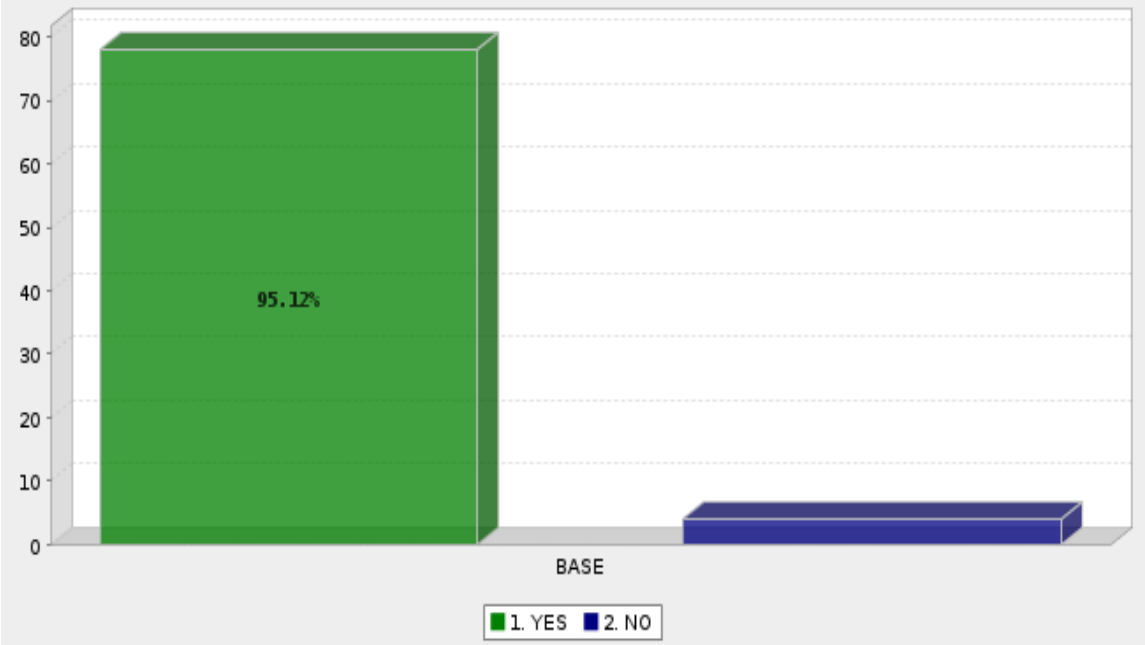


Figure 1.2.3
Percentage usage of Clomiphene Citrate/Letrozole for ovulation induction.

Table 1.2.3
Percentage usage of Clomiphene Citrate/Letrozole for ovulation induction.

Answer	**Percent (%)**	**Count(N)**
YES	95%	78
NO	5%	4
Total	100%	82
Mean	1.05	
Confidence Interval @ 95%	[1.002 - 1.096]	
Standard Deviation	0.217	
Standard Error	0.024	

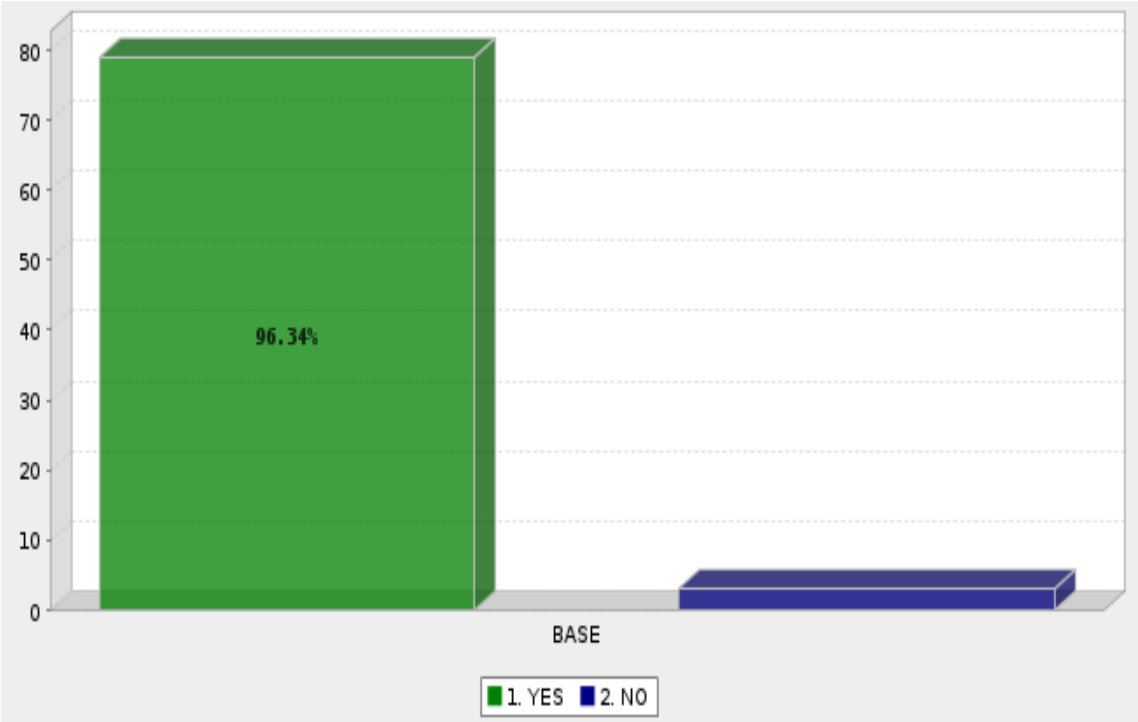


Figure 1.2.4
Percentage usage of Diagnostic Hysteroscopy/Laparoscopy

Figure 1.2.4 shows that 96% centers out of the 82 IVF centers practice Diagnostic Laparoscopy and Hysteroscopy procedures in their respective ivf / fertility centre and the raw statistics are displayed in Table 1.2.4.

Table 1.2.4
Percentage usage of Diagnostic Hysteroscopy/Laparoscopy.

Answer	**Percent (%)**	**Count(N)**
YES	96%	79
NO	4%	3
Total	100%	82
Mean	1.04	
Confidence Interval @ 95%	[0.996 - 1.077]	
Standard Deviation	0.189	
Standard Error	0.021	

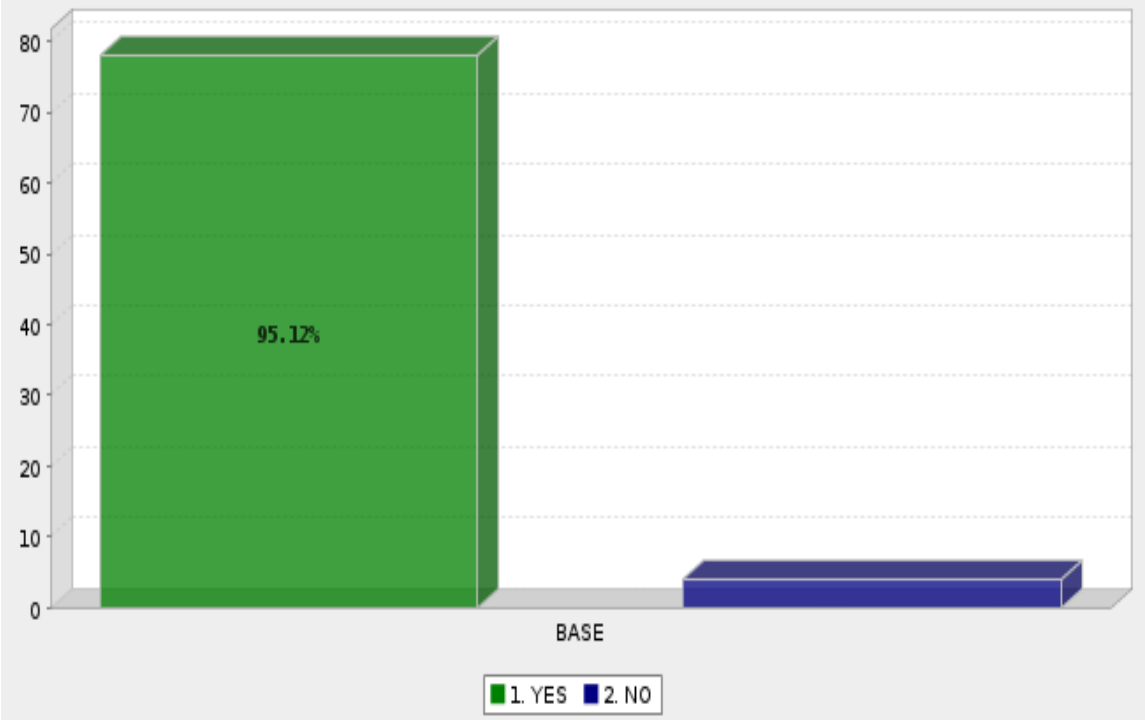


Figure 1.2.5
Percentage usage of Fertility Enhancing Laparoscopic Surgeries

Figure 1.2.5 shows that 95% centers out of the 82 IVF centers practice Fertility Enhancing laparoscopic surgeries procedures in their respective IVF / fertility centre and the raw statistics of the same are displayed in Table 1.2.5.

Table 1.2.5
Percentage usage of Fertility Enhancing Laparoscopic Surgeries.

Answer	**Percent (%)**	**Count(N)**
YES	95%	78
NO	5%	4
Total	100%	82
Mean	1.05	
Confidence Interval @ 95%	[1.002 - 1.096]	

Standard Deviation	0.217
Standard Error	0.024

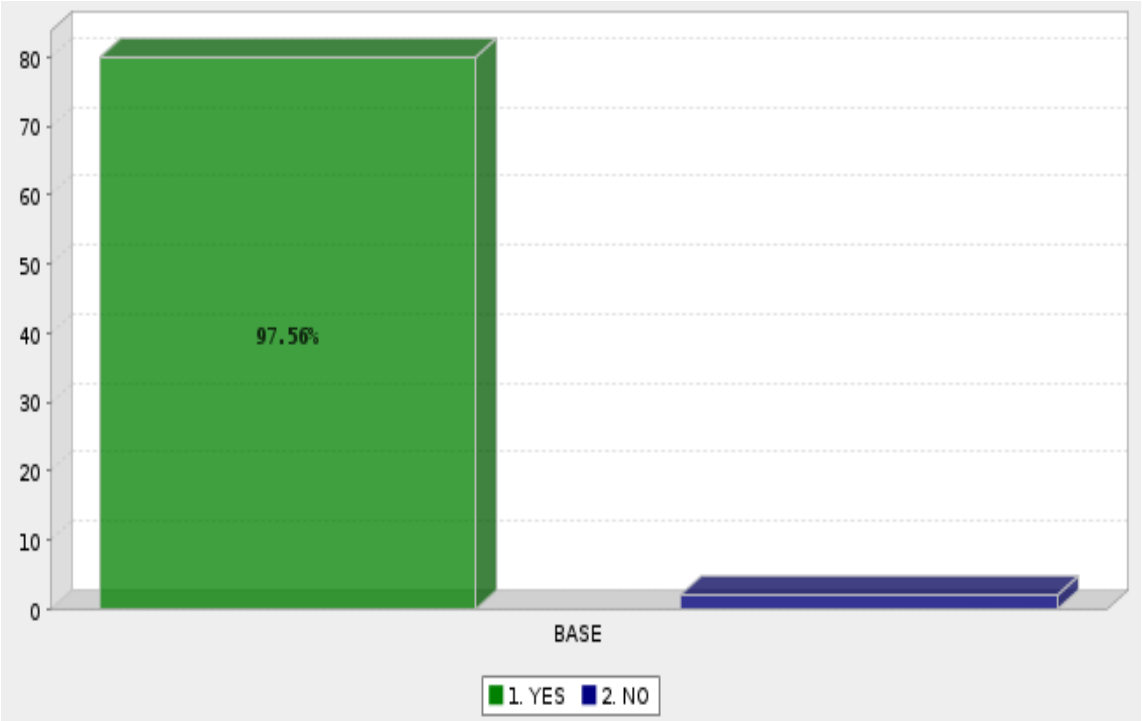


Figure 1.2.6
Percentage Usage of Intra Uterine Insemination(IUI).

Figure 1.2.6 shows that 97% centers out of the 82 IVF centers practice intrauterine insemination procedures in their respective IVF / fertility centre and the raw statistics are displayed in Table 1.2.6.

Tabel 1.2.6
Percentage Usage of Intra Uterine Insemination(IUI).

Answer	**Percent (%)**	**Count(N)**
YES	98%	80
NO	2%	2
Total	100%	82
Mean	1.02	
Confidence Interval @ 95%	[0.991 - 1.058]	
Standard Deviation	0.155	
Standard Error	0.017	

Figure 4.2.7 shows that 94% centers out of the 82 IVF centers practice Conventional Insemination procedures in their respective IVF / fertility centre and the raw statistics are displayed in Table 1.2.7.

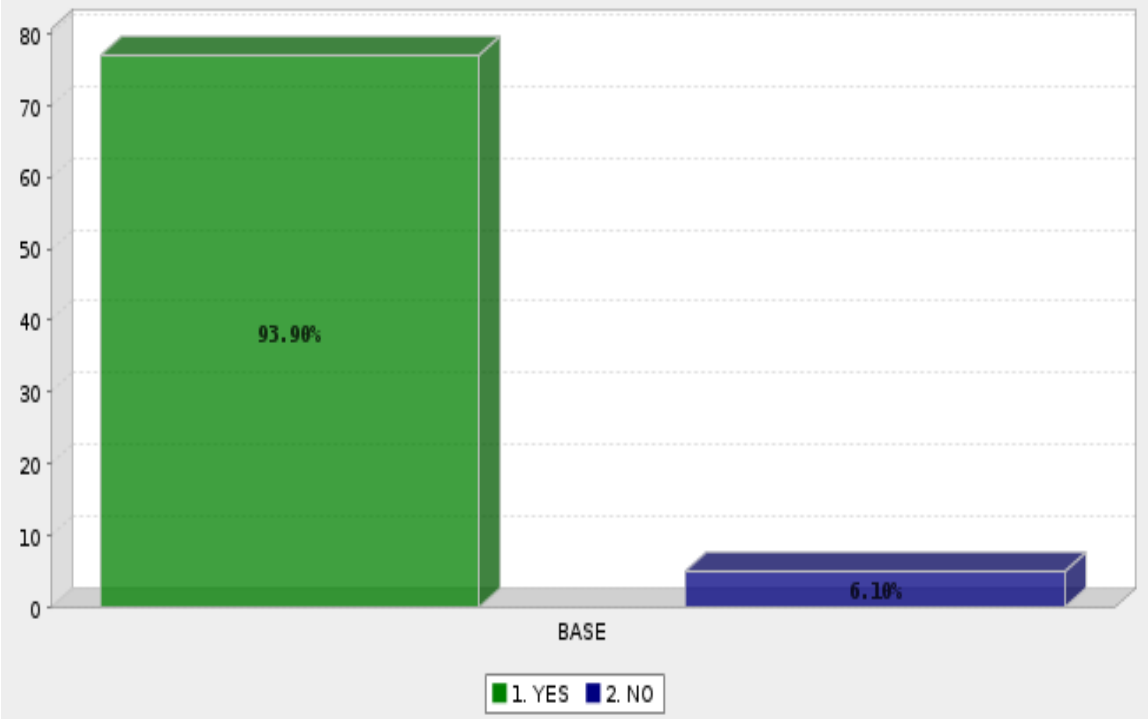


Figure 1.2.7
Percentage usage of Conventional Insemination(IVF).

Table 1.2.7 displays in tabular form that 94% centers out of the 82 IVF centers / fertility centers practice Conventional Insemination procedures in their respective IVF / fertility centre out of the 82 centers.

Table 1.2.7
Percentage usage of Conventional Insemination(IVF).

Answer	**Percent (%)**	**Count(N)**
YES	94%	77
NO	6%	5
Total	100%	82
Mean	1.06	
Confidence Interval @ 95%	[1.009 - 1.113]	
Standard Deviation	0.241	
Standard Error	0.027	

Figure 1.2.8 shows that 97.56% centers out of the 82 IVF centers practice Intra-cytoplasmic sperm injection procedures in their respective IVF / fertility centres and the raw statistics are displayed in Table 1.2.8.

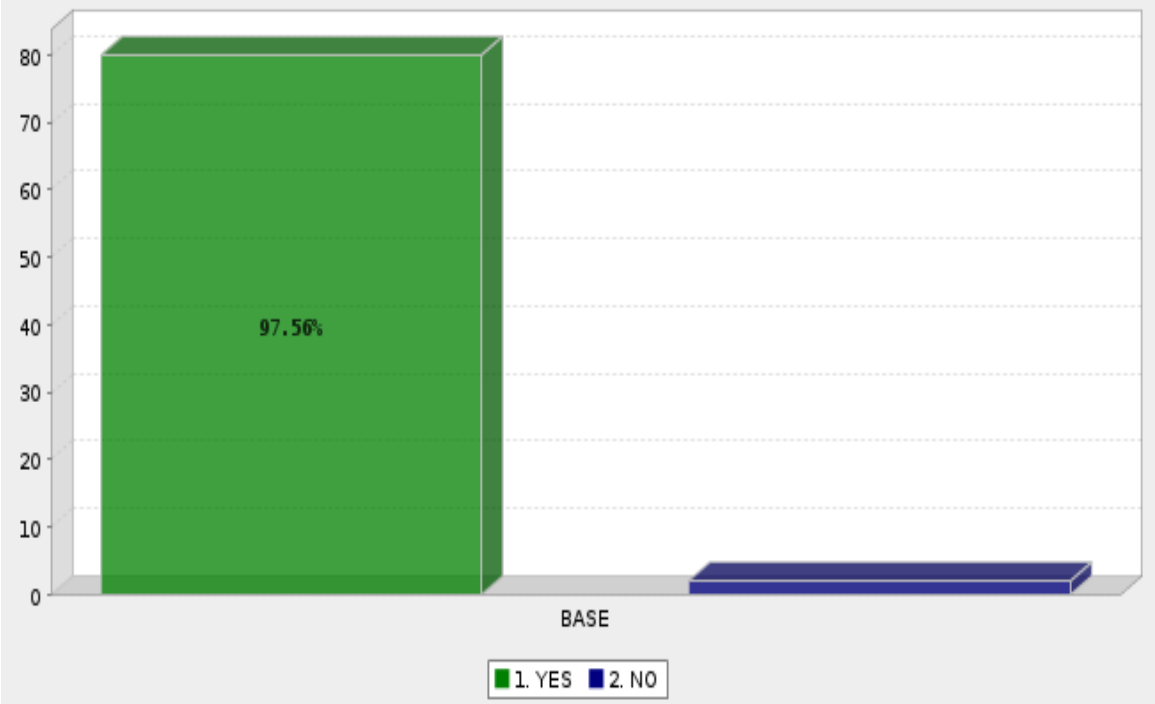


Figure 1.2.8
Percentage Usage of Intra-Cytoplasmic Sperm Injection(ICSI).

Table 1.2.8 displays that 98% of the centre out of the 82 IVF centers participated in the survey practice usage of ICSI (Intra-cytoplasmic sperm injection) procedures and offer this service to the patients visiting to their respective centre.

Less than 2% of the rest out of the 82 IVF centers do not practice or offer Intra-cytoplasmic sperm injection procedures in their respective fertility / IVF centre. Tabular data for the same is mentioned in Table 1.2.8

Table 1.2.8
Percentage Usage of Intra-Cytoplasmic Sperm Injection(ICSI).

Answer	Percent (%)	Count(N)
YES	98%	80
NO	2%	2
Total	100%	82
Mean	1.02	
Confidence Interval @ 95%	[0.991 - 1.058]	
Standard Deviation	0.155	
Standard Error	0.017	

Figure 1.2.9 shows that 46% of centers out of the 82 IVF centers participated in the survey, practice Pre-implantation genetic testing procedures and the raw statistics of the same are displayed in below Table 1.2.9

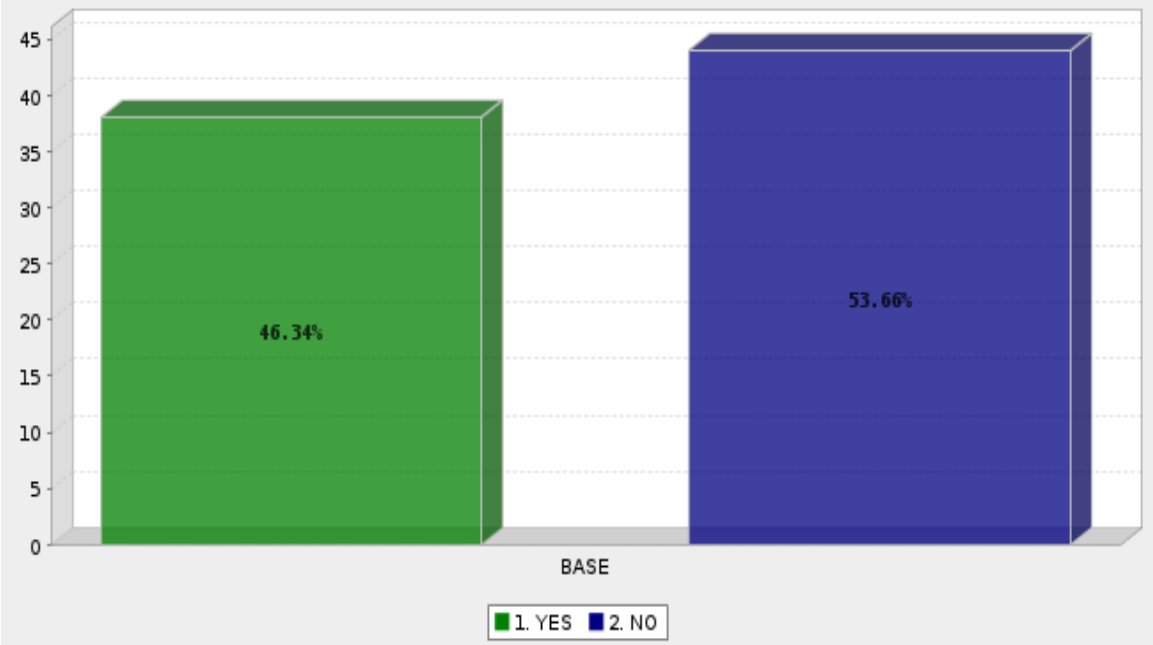


Figure 1.2.9
Percentage usage of Pre Implantation Genetic Testing.

Table 1.2.9
Percentage usage of Pre Implantation Genetic Testing.

Answer	**Percent (%)**	**Count(N)**
YES	46%	38
NO	54%	44
Total	100%	82
Mean	1.54	
Confidence Interval @ 95%	[1.428 - 1.645]	
Standard Deviation	0.502	
Standard Error	0.055	

Figure 1.2.10 shows that 68% centers out of the 82 IVF centers practice assisted hatching procedures in their respective IVF/ Fertility Centre and the raw statistics are displayed in Table 1.2.10

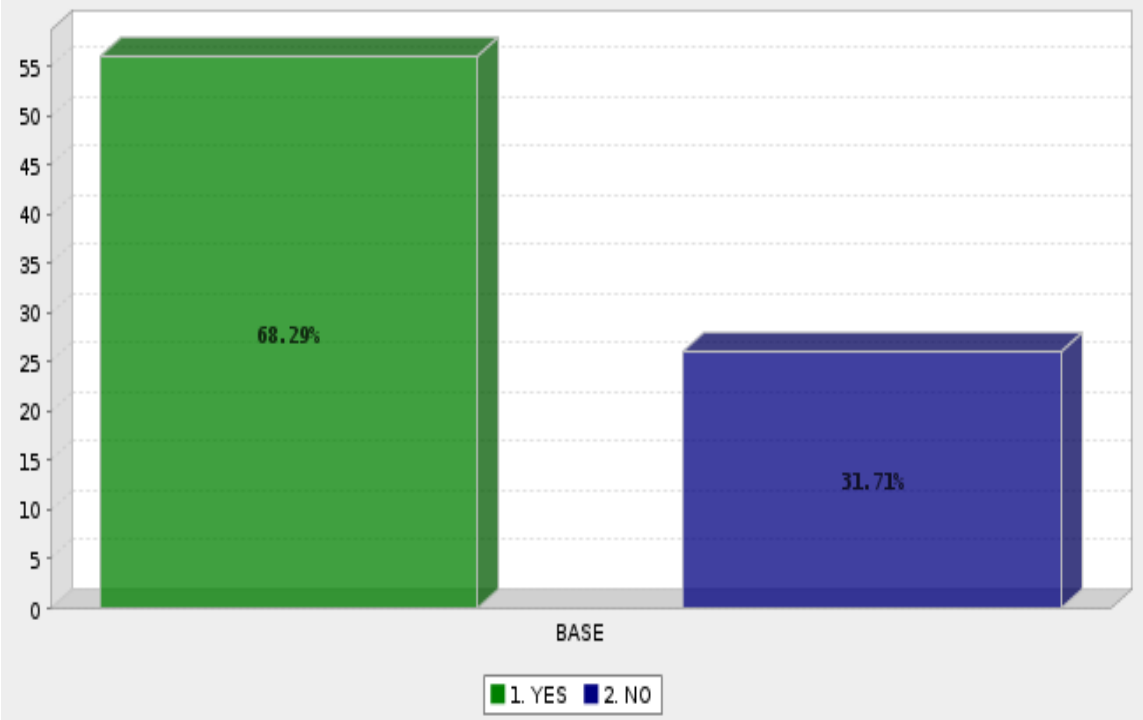


Figure 1.2.10
Percentage Usage of Assisted Hatching.

Table 1.2.10 displays in tabular form that 68% of the respondent centre are using assisted hatching and offering the services to the patinets and 32% of the centre do not practice assisted hatcing and do not offer the service to the patinet may be due to non availablity or do not possess the medical laser.

Tabel 1.2.10
Percentage Usage of Assisted Hatching.

Answer	**Percent (%)**	**Count(N)**
YES	68%	56
NO	32%	26
Total	100%	82
Mean	1.32	
Confidence Interval @ 95%	[1.216 - 1.418]	
Standard Deviation	0.468	
Standard Error	0.052	

4.3 Matrix scorecard for cases per month at hospital/center

Figure 2.1 displays the average number of procedures per intervention the respondents filled in the survey that are practiced in their respective Fertility centres /IVF Centres.

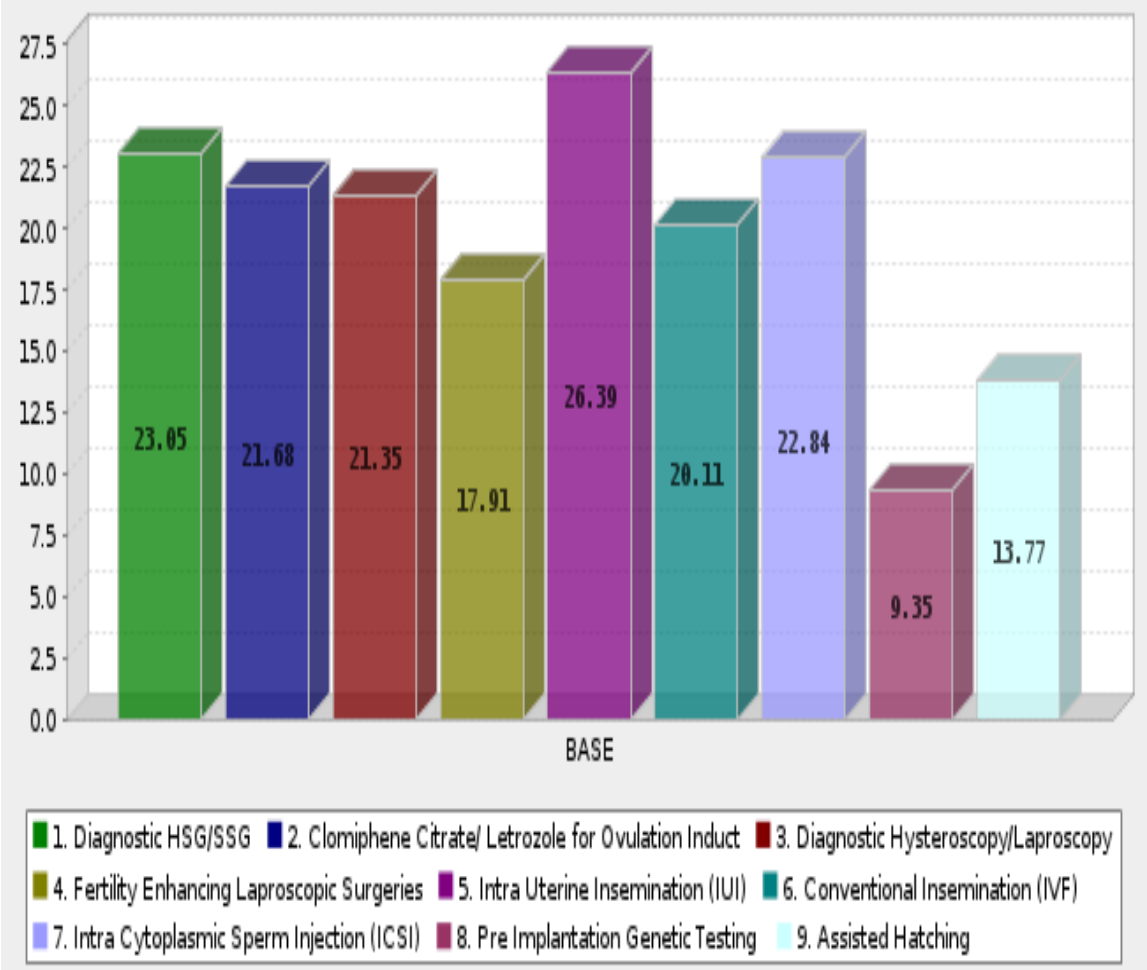


Figure 2.1
Matrix Score card for cases per month at hospital/Center.

Table 2.1 also displays the descriptive statistics for the survey results per intervention of the nine interventions.

Table 2.1
Matrix Score card for cases per month at hospital/Center.

S N	Question	Count	Score
1.	Diagnostic HSG/SSG	82	23.049
2.	Clomiphene Citrate/ Letrozole for Ovulation Induction	82	21.683
3.	Diagnostic Hysteroscopy/Laparoscopy	82	21.354
4.	Fertility Enhancing Laparoscopic Surgeries	82	17.915
5.	Intra Uterine Insemination (IUI)	82	26.390
6.	Conventional Insemination (IVF)	82	20.110
7.	Intra Cytoplasmic Sperm Injection (ICSI)	82	22.841
8.	Pre-Implantation Genetic Testing	82	9.350
9.	Assisted Hatching	82	13.765
Average			**19.606**

An Average of 19-20 cases is done per month for the centers that have entered the survey results. It is noted that higher interest for cost optimization may lie in centers with an average of <250 cycles per annum. Due to the fragmented nature of the Fertility market patient-wise in India, almost 70% of centers fall in this category.

This gives us a good representation of small to medium centers in India. However, the large centers are automatically excluded from the analysis. Another representative survey should be conducted in the future as a research direction to extend the analysis to these stakeholders who hold a higher opportunity to provide reduction of costs and access of care to the Indian subcontinent.

4.4 Cost associated per patient/Procedure/Event for Treatment intervention

Figure 2.2 displays the cost for hospital associated with each procedure/intervention per patient as per survey results on average.

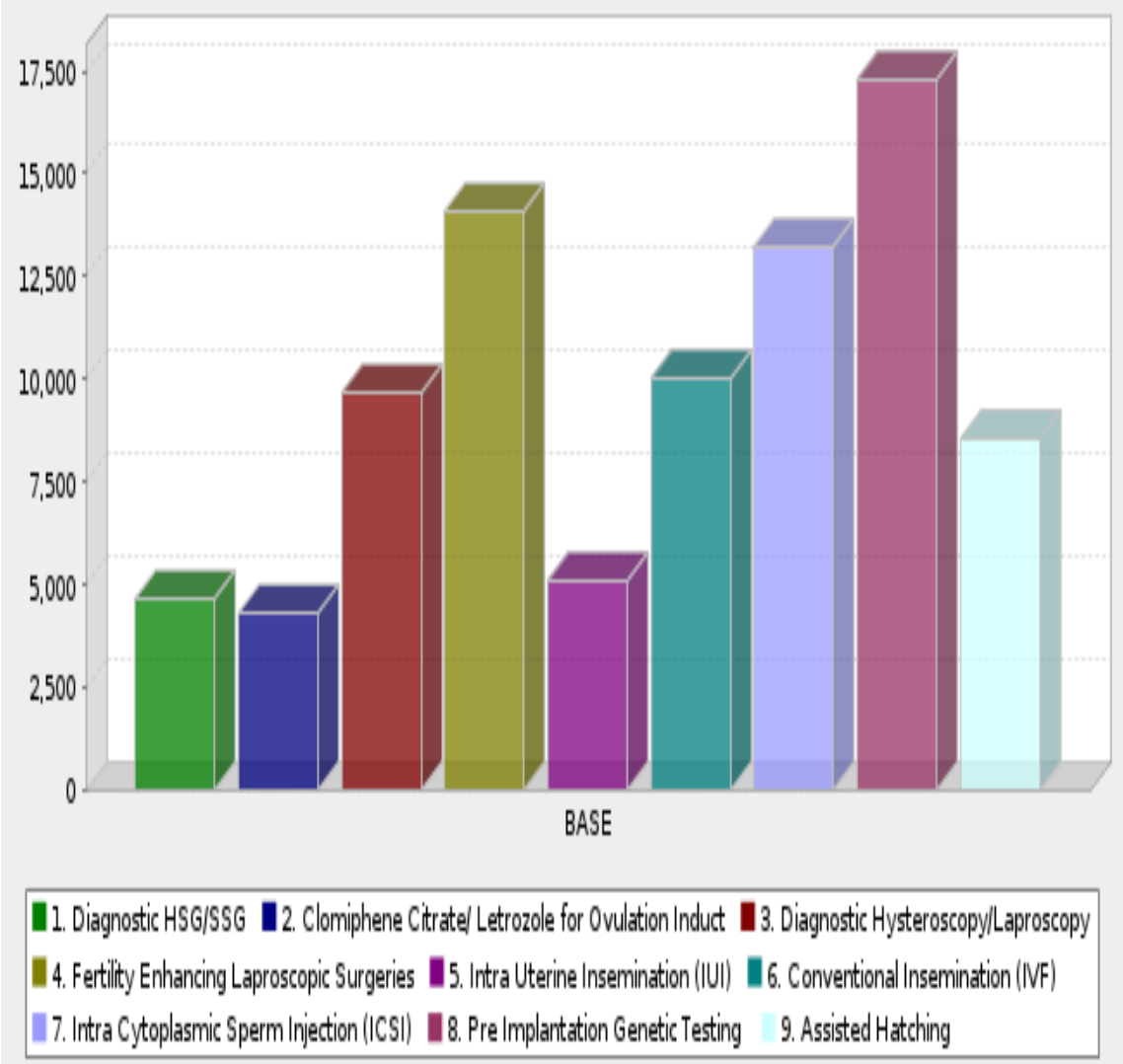


Figure 2.2
Cost associated per patient/Procedure/Event for Treatment intervention.

Table 2.2 is displaying the descriptive statistics for the cost for hospital associated with each procedure/intervention per patient as per survey results on average.

Table 2.2
Overall Matrix scorecard for Cost associated per patient /Procedure /Event for Treatment intervention.

SN	Question	Count	Score
1.	Diagnostic HSG/SSG	82	4,621.951
2.	Clomiphene Citrate/ Letrozole for Ovulation Induction	82	4,268.292
3.	Diagnostic Hysteroscopy/Laparoscopy	82	9,670.731
4.	Fertility Enhancing Laparoscopic Surgeries	81	14,074.074
5.	Intra Uterine Insemination (IUI)	82	5,109.756
6.	Conventional Insemination (IVF)	82	10,036.585
7.	Intra Cytoplasmic Sperm Injection (ICSI)	82	13,219.512
8.	Pre-Implantation Genetic Testing	81	17,333.334
9.	Assisted Hatching	81	8,567.901
Average			**9,655.793**

4.5 Cost saving associated with each Intervention in practice per patient

Figure 2.3 is displaying the cost saving per patient associated for each cost saving intervention practiced per patient as per survey results.

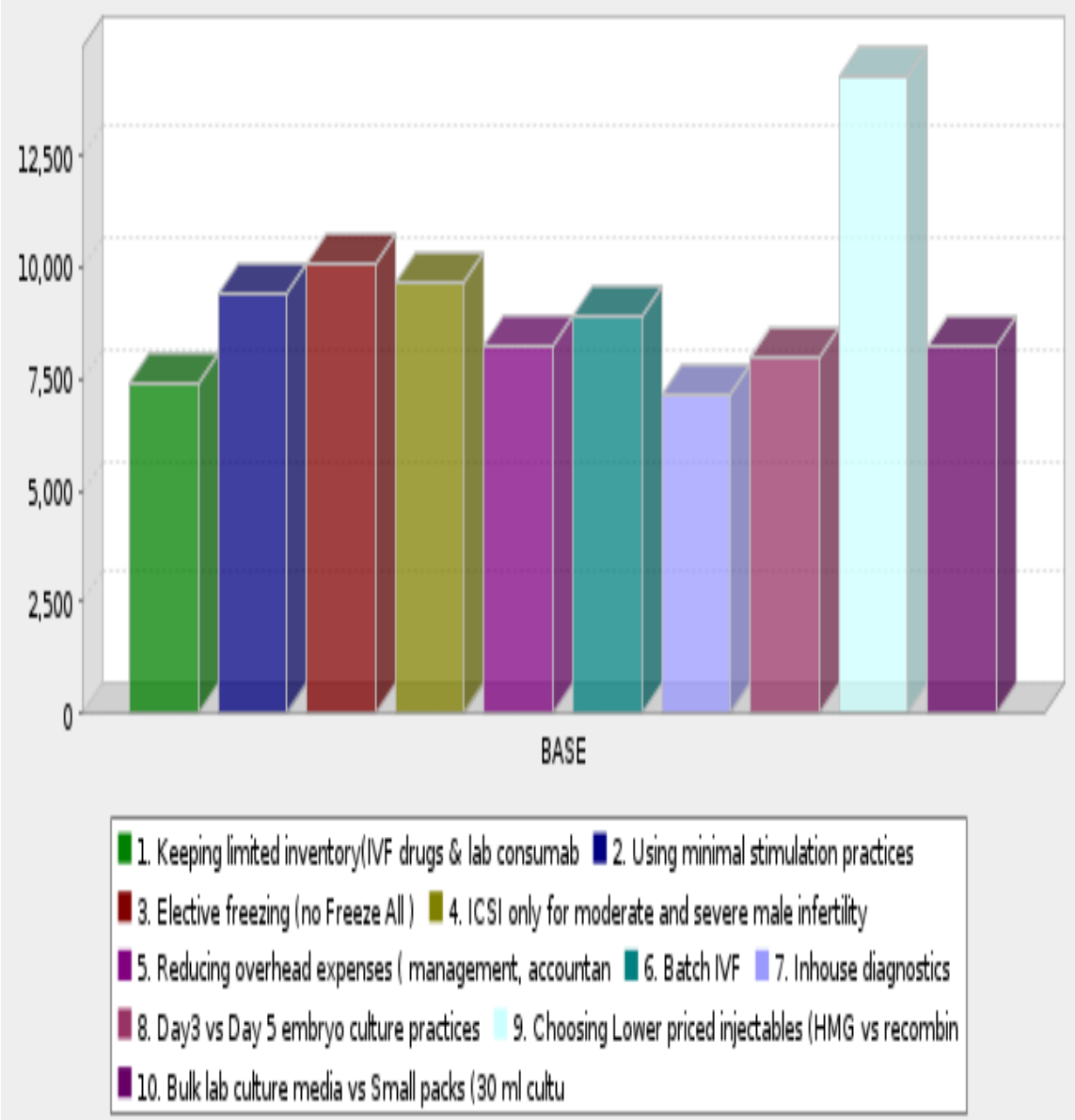


Figure 2.3
Cost saving associated with each Intervention in practice per patient.

Table 2.3 is displaying the descriptive statistics of cost saving per patient associated for each cost saving intervention practiced per patient as per survey results derived from the response of the survey respondents.

Table 2.3
Matrix scorecard for Cost saving associated with each Intervention in practice per patient.

SN	Question	Count	Score
1.	Keeping limited inventory (IVF drugs & lab consumables)	82	7,414.634
2.	Using minimal stimulation practices	82	9,390.244
3.	Elective freezing (no Freeze All)	82	10,048.780
4.	ICSI only for moderate and severe male infertility	82	9,634.146
5.	Reducing overhead expenses (management, accountancy, reception etc.)	82	8,256.098
6.	Batch IVF	81	8,901.234
7.	In-house diagnostics	82	7,134.146
8.	Day3 vs. Day 5 embryo culture practices	82	7,939.024
9.	Choosing Lower priced injectable (hMG vs. recombinant, biosimilars vs. original formulations)	82	14,243.902
10.	Bulk lab culture media vs. small packs (30 ml culture media vs. 10ml, Large Vitrification kits vs. small kits)	81	8,197.531

4.6 Average Ranking for cost saving parameters

Figure 2.4 is displaying the bar graph analysis for average ranking given by survey respondents by ease of use and practice for each cost saving intervention as per survey results on average.

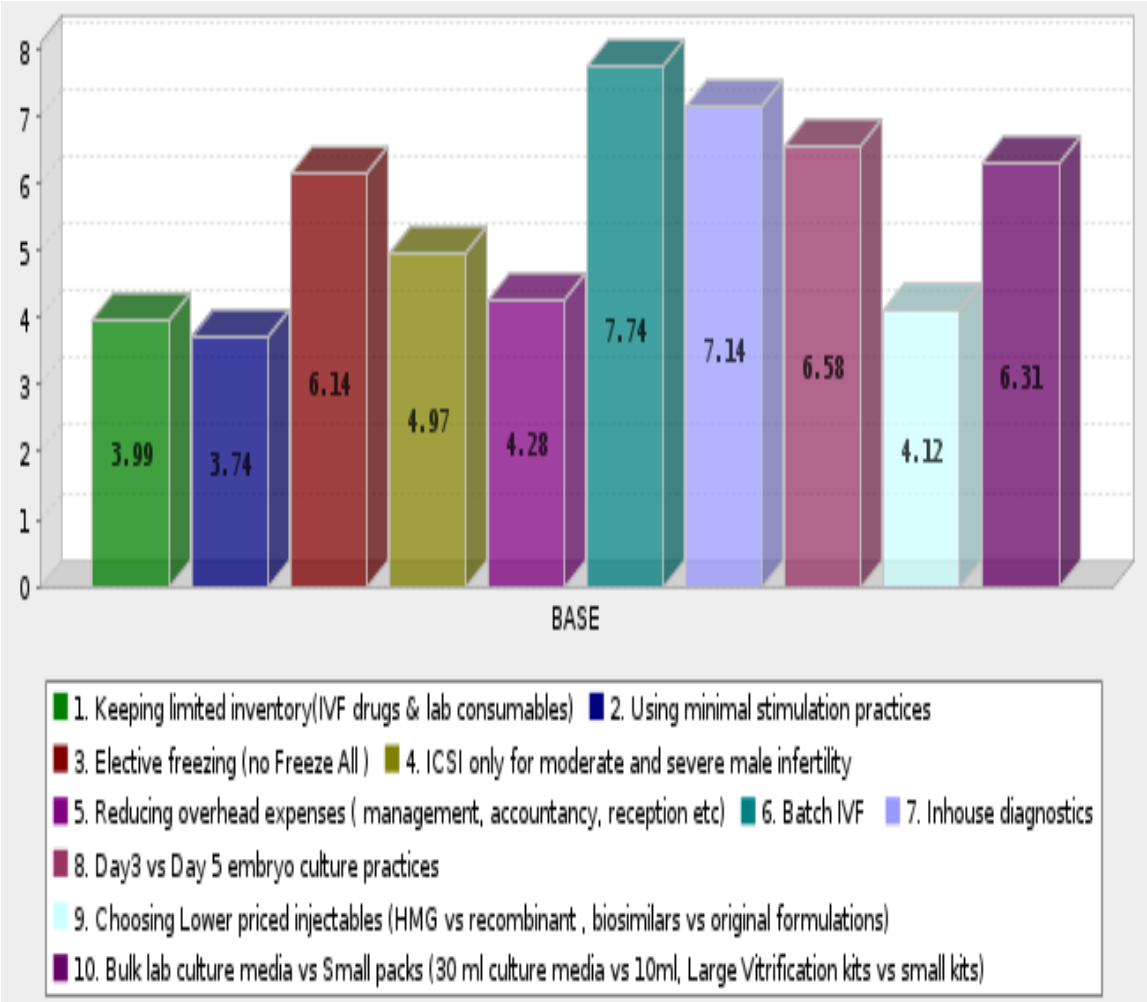


Figure 2.4
Average Ranking for cost saving parameters.

Table 2.4 is displaying the descriptive statistics for average ranking given by survey respondents by ease of use and practice for each cost saving intervention as per survey results on average.

Table 2.4
Average Ranking for cost saving parameters.

SN	Particulars	Average Rank
1	Keeping limited inventory (IVF Drugs & Lab consumables)	3.99
2	Using minimal stimulation practices	3.74
3	Elective freezing (no freeze all)	6.14
4	ICSI only for moderate and severe male infertility	4.97
5	Reducing overhead expenses (Management, Accountancy, reception etc.)	4.28
6	Batch IVF	7.74
7	In-house diagnostics	7.14
8	Day3 vs. Day 5 embryo culture practices	6.58
9	Choosing Lower priced injectable (hMG vs. Recombinant, Biosimilars vs. original formulation)	4.12
10	Bulk lab culture media vs. small packs (culture media 30 ml vs. 10 ml, large vitrification kits vs. small kits)	6.31

Table 2.4.1displays the number of survey respondents and the percentage of each response given ranking for the various points mentioned in the table. The point ‘Keeping Limited Inventory’. Column 1 is Ranking 1 while Column 10 is Ranking 10 in corresponding order.

Table 2.4.1
Percentage of Keeping limited inventory (IVF Drugs & Lab consumables).

1)	**Keeping limited inventory (IVF Drugs & Lab consumables)**	
Response	12	15.00%
	1	1.25%
	12	15.00%
	13	16.25%
	13	16.25%
	12	15.00%
	3	3.75%
	8	10.00%
	6	7.50%
	0	0.00%
Total	**80**	**100.00%**

Table 2.4.2 displays the number of survey respondents and the percentage of each response given as ranking to the point ‘Using minimal stimulation practices. Column 1 is Ranking 1 while Column 10 is Ranking 10 in corresponding order.

Table 2.4.2
Percentage of Using minimal stimulation practices

2)	**Using minimal stimulation practices**	
Response	17	21.25%
	3	3.75%
	17	21.25%
	11	13.75%
	12	15.00%
	3	3.75%
	4	5.00%
	7	8.75%
	5	6.25%
	1	1.25%
Total	**80**	**100.00%**

Table 2.4.3 displays the number of survey respondents and the percentage of each response given ranking to 'Elective freezing (no freeze all)'. Column 1 is Ranking 1 while Column 10 is Ranking 10 in corresponding order.

Table 2.4.3
Percentage of Elective freezing (no freeze all).

3)	**Elective freezing (no freeze all)**	
Response	5	6.25%
	6	7.50%
	1	1.25%
	11	13.75%

	5	6.25%
	5	6.25%
	12	15.00%
	14	17.50%
	13	16.25%
	8	10.00%
Total	**80**	**100.00%**

Table 2.4.4 displays the number of survey respondents and the percentage of each response given ranking to 'ICSI only for moderate and severe male infertility'. Column 1 is Ranking 1 while Column 10 is Ranking 10 in corresponding order.

Table 2.4.4
Percentage of ICSI only for moderate and severe male infertility

4)	**ICSI only for moderate and severe male infertility**	
Response	4	5.00%
	1	1.25%
	10	12.50%
	10	12.50%
	18	22.50%
	7	8.75%
	7	8.75%
	7	8.75%
	8	10.00%
	8	10.00%
Total	**80**	**100.00%**

Table 2.4.5 displays the number of survey respondents and the percentage of each response given ranking to Reducing overhead expenses (Management, Accountancy, reception etc.)'. Column 1 is Ranking 1 while Column 10 is Ranking 10 in corresponding order.

Table 2.4.5
Percentage for reducing overhead expenses (Management, Accountancy, reception etc.).

5)	**Reducing overhead expenses (Management, Accountancy, reception etc.)**	
Response	13	16.25%
	2	2.50%
	18	22.50%
	7	8.75%
	2	2.50%
	17	21.25%
	4	5.00%
	6	7.50%
	6	7.50%
	5	6.25%
Total	**80**	**100.00%**

Table 2.4.6 displays the number of survey respondents and the percentage of each response given ranking to 'Batch IVF'. Column 1 is Ranking 1 while Column 10 is Ranking 10 in corresponding order.

Table 2.4.6
Percentage of Batch IVF

6)	**Batch IVF**	
Response	2	2.50%
	30	37.50%
	3	3.75%
	1	1.25%
	3	3.75%
	2	2.50%
	16	20.00%
	6	7.50%
	5	6.25%
	12	15.00%
Total	80	100.00%

Table 2.4.7 displays the number of survey respondents and the percentage of each response given ranking to 'In House Diagnostics'. Column 1 is Ranking 1 while Column 10 is Ranking 10 in corresponding order.

Table 2.4.7
Percentage for In House Diagnostics

7)	**In-house diagnostics**	
Response	3	3.75%
	11	13.75%
	2	2.50%
	4	5.00%
	7	8.75%
	5	6.25%

	4	5.00%
	14	17.50%
	3	3.75%
	27	33.75%
Total	80	100.00%

Table 2.4.8 displays the number of survey respondents and the percentage of each response given ranking to ‘Day 3 vs. Day 5 embryo culture practices. Column 1 is Ranking 1 while Column 10 is Ranking 10 in corresponding order.

Table 2.4.8
Percentage of Day 3vs Day 5 Embryo culture practices.

8)	**Day 3 vs. Day 5 embryo culture practices**	
Response	0	0.00%
	5	6.25%
	2	2.50%
	5	6.25%
	4	5.00%
	12	15.00%
	15	18.75%
	9	11.25%
	24	30.00%
	4	5.00%
Total	80	100.00%

Table 2.4.9 displays the number of survey respondents and the percentage of each response given ranking to ‘Choosing Lower priced injectable (hMG vs. Recombinant,

Biosimilars vs. original formulation)'. Column 1 is Ranking 1 while Column 10 is Ranking 10 in corresponding order.

Table 2.4.9
Percentage for choosing lower priced injectable.

9)	**Choosing Lower priced injectable (hMG vs. Recombinant, Biosimilars vs. original formulation)**	
Response	22	27.50%
	3	3.75%
	11	13.75%
	12	15.00%
	5	6.25%
	4	5.00%
	5	6.25%
	4	5.00%
	4	5.00%
	10	12.50%
Total	80	100.00%

Table 2.4.10 displays the number of survey respondents and the percentage of each response given ranking to 'Bulk lab culture media vs. small packs (culture media 30 ml vs. 10 ml, large vitrification kits vs. small kits)'. Column 1 is Ranking 1 while Column 10 is Ranking 10 in corresponding order.

Table 2.4.10
Percentage for choosing culture media bulk vs. small.

10)	**Bulk lab culture media vs. small packs (culture media 30 ml vs. 10 ml, large vitrification kits vs. small kits)**	
Response	2	2.50%
	18	22.50%
	4	5.00%
	6	7.50%
	11	13.75%
	13	16.25%
	10	12.50%
	5	6.25%
	6	7.50%
	5	6.25%
Total	80	100.00%

4.7 Rating each intervention in terms of feasibility of Use

Figure 2.5 displays in graphical format the average ranking as per survey respondents given to each cost saving intervention based on feasibility and ease of use in Fertility Center setting.

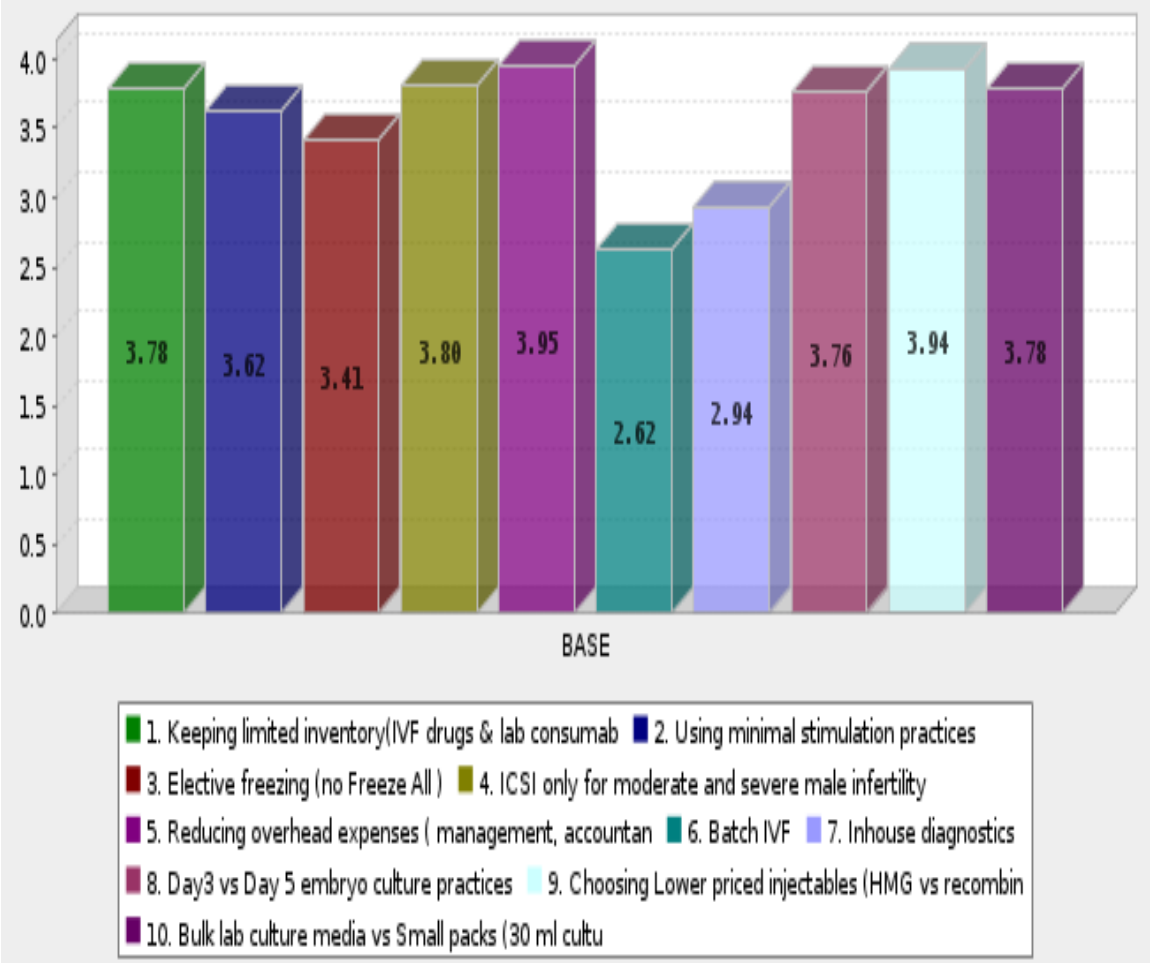


Figure 2.5
Score card of each intervention in term of feasibility of use.

Table 2.5 shows descriptive statistics of average ranking given to each cost saving intervention by Survey respondents.

Table 2.5
Overall Matrix scorecard each intervention in terms of feasibility of use.

Sr. No	Question	Count	Score
1.	Keeping limited inventory (IVF drugs and lab consumables)	82	3.780
2.	Using minimal stimulation practices	82	3.622
3.	Elective freezing (no Freeze All)	82	3.415
4.	ICSI only for moderate and severe male infertility	82	3.805
5.	Reducing overhead expenses (management, accountancy, reception etc.)	82	3.951
6.	Batch IVF	82	2.622
7.	In-house diagnostics	82	2.939
8.	Day3 vs. Day 5 embryo culture practices	82	3.756
9.	Choosing Lower priced injectable (hMG vs. recombinant, biosimilars vs. original formulations)	82	3.939
10.	Bulk lab culture media vs. small packs (30 ml culture media vs. 10ml, Large Vitrification kits vs. small kits)	82	3.780
Average			**3.561**

Figure 2.5.1 depicts Five-point Likert scale graphical representation is shown for intervention 'Keeping Limited Inventory' as selected by survey respondents.

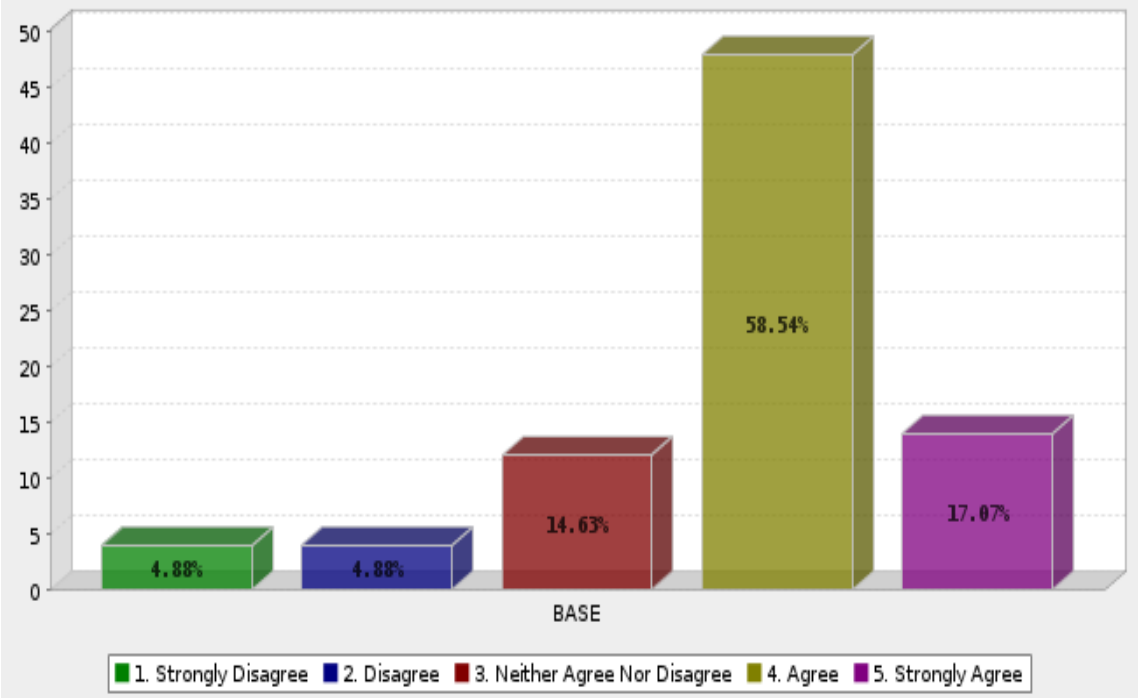


Figure 2.5.1
Percentage for keeping limited inventory (IVF drugs & lab consumables).

Table 2.5.1- Five-point Likert scale descriptive statistics is shown for 'Keeping Limited Inventory' by survey respondents.

Table 2.5.1
Percentage for keeping limited inventory (IVF drugs & lab).

Answer	**Percent (%)**	**Count(N)**
Strongly Disagree	5%	4
Disagree	5%	4
Neither Agree nor Disagree	15%	12
Agree	59%	48

Strongly Agree	17%	14
Total	100%	82
Mean	3.78	
Confidence Interval @ 95%	[3.574 - 3.987]	
Standard Deviation	0.956	
Standard Error	0.106	

Figure 2.5.2 depicts Five-point Likert scale graphical representation is shown for intervention 'Using minimal stimulation practices' as selected by survey respondents in their respective IVF / fertility centre.

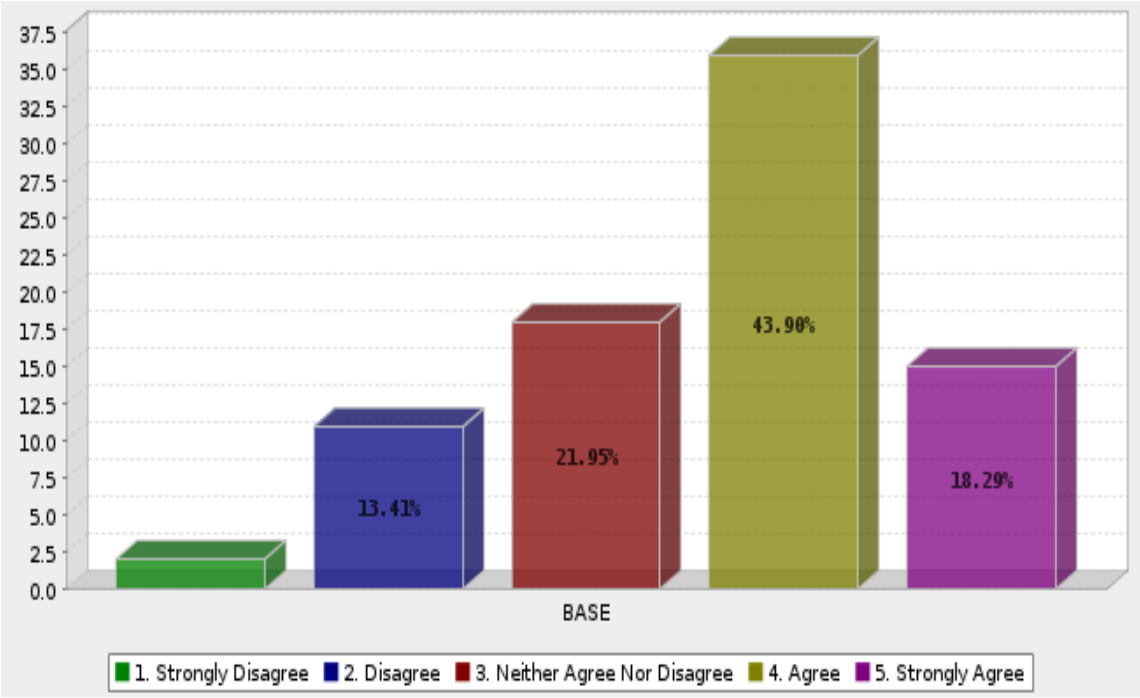


Figure 2.5.2
Percentage for using Minimum Stimulation practices.

Table 2.5.2 Five-point Likert scale descriptive statistics is shown for 'Using minimal stimulation practices' by survey respondents in their respective IVF / fertility centre.

Table 2.5.2
Percentage for using Minimum Stimulation practices.

Answer	**Percent (%)**	**Count(N)**
Strongly Disagree	2%	2
Disagree	13%	11
Neither Agree nor Disagree	22%	18
Agree	44%	36
Strongly Agree	18%	15
Total	100%	82
Mean	3.62	
Confidence Interval @ 95%	[3.402 - 3.841]	
Standard Deviation	1.014	
Standard Error	0.112	

Figure 2.5.3 depicts Five-point Likert scale graphical representation is shown for intervention 'Elective freezing (no Freeze All)' as selected by survey respondents.

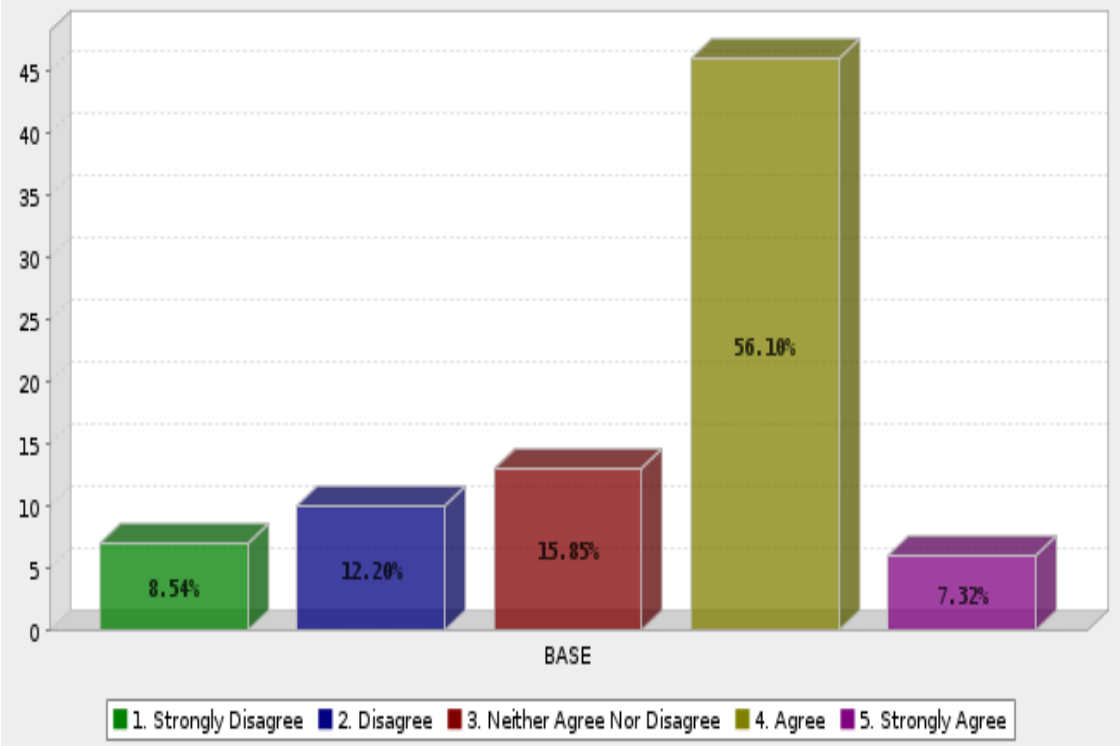


Figure 2.5.3
Percentage for Elective freezing (no Freeze All).

Table 2.5.3 Five-point Likert scale descriptive statistics is shown for 'Elective freezing (no Freeze All)' by survey respondents.

Table 2.5.3
Percentage for Elective freezing (no Freeze All).

Answer	**Percent (%)**	**Count(N)**
Strongly Disagree	9%	7
Disagree	12%	10
Neither Agree nor Disagree	16%	13
Agree	56%	46
Strongly Agree	7%	6
Total	100%	82
Mean	3.41	

Confidence Interval @ 95%	[3.182 - 3.648]
Standard Deviation	1.077
Standard Error	0.119

Figure 2.5.4 depicts Five-point Likert scale graphical representation is shown for intervention 'ICSI only for moderate and severe male infertility' as selected by survey respondents.

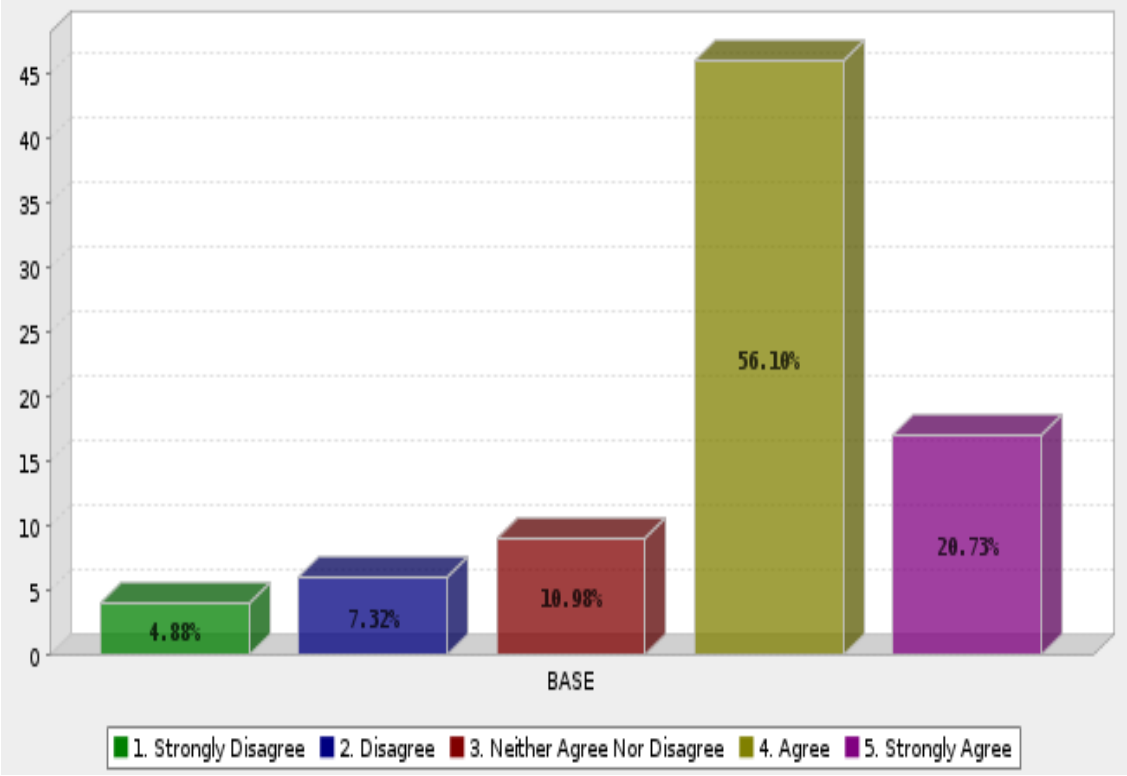


Figure 2.5.4
Percentage ICSI only for moderate and severe male infertility

Table 2.5.4 Five-point Likert scale descriptive statistics is shown for 'ICSI only for moderate and severe male infertility' by survey respondents.

Table 2.5.4
Percentage ICSI only for moderate and severe male infertility.

Answer	**Percent (%)**	**Count(N)**
Strongly Disagree	5%	4
Disagree	7%	6
Neither Agree nor Disagree	11%	9
Agree	56%	46
Strongly Agree	21%	17
Total	100%	82
Mean	3.80	
Confidence Interval @ 95%	[3.586 - 4.024]	
Standard Deviation	1.012	
Standard Error	0.112	

Figure 2.5.5 depicts Five-point Likert scale graphical representation is shown for intervention ‘Reducing overhead expenses (management, accountancy, reception etc.)’ as selected by survey respondents.

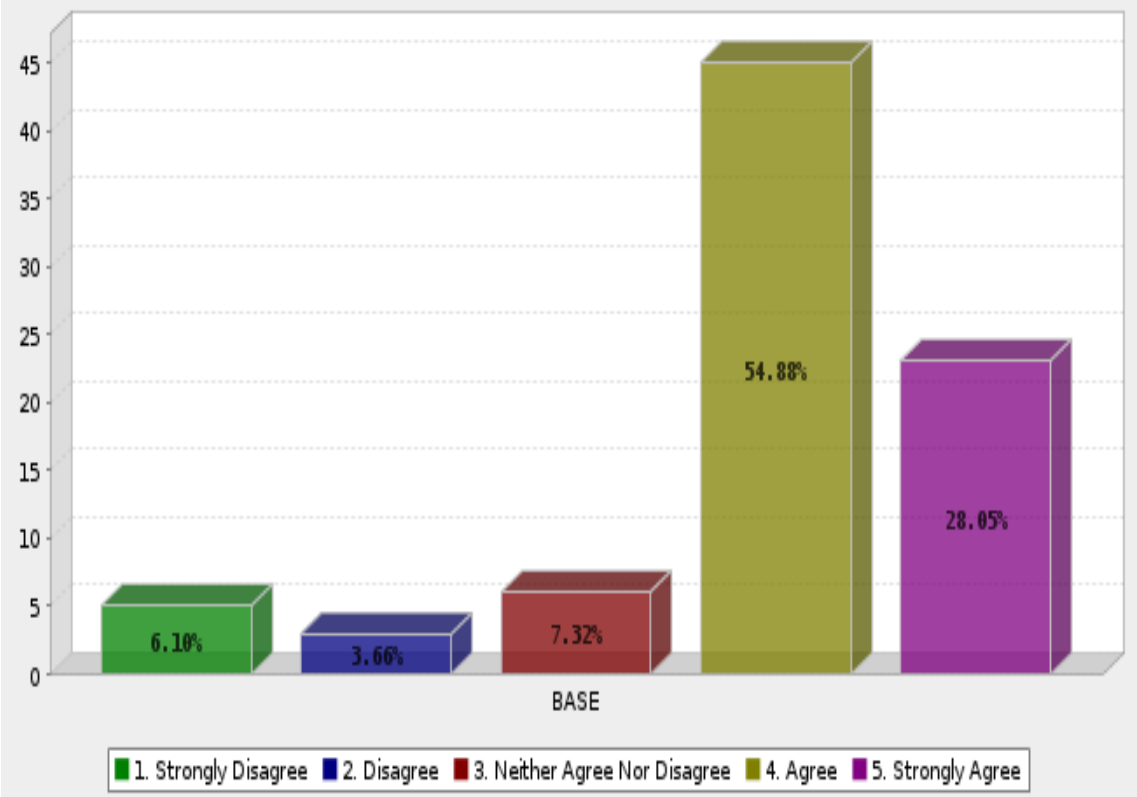


Figure 2.5.5
Percentage for reducing overhead expenses (management, accountancy, reception etc.)

Table 2.5.5 Five-point Likert scale descriptive statistics is shown for 'Reducing overhead expenses (management, accountancy, reception etc.)' by survey respondents.

Table 2.5.5
Percentage for reducing overhead expenses (management, accountancy, reception etc.).

Answer	**Percent (%)**	**Count(N)**
Strongly Disagree	6%	5
Disagree	4%	3
Neither Agree nor Disagree	7%	6
Agree	55%	45
Strongly Agree	28%	23
Total	100%	82

Mean	3.95
Confidence Interval @ 95%	[3.728 - 4.174]
Standard Deviation	1.029
Standard Error	0.114

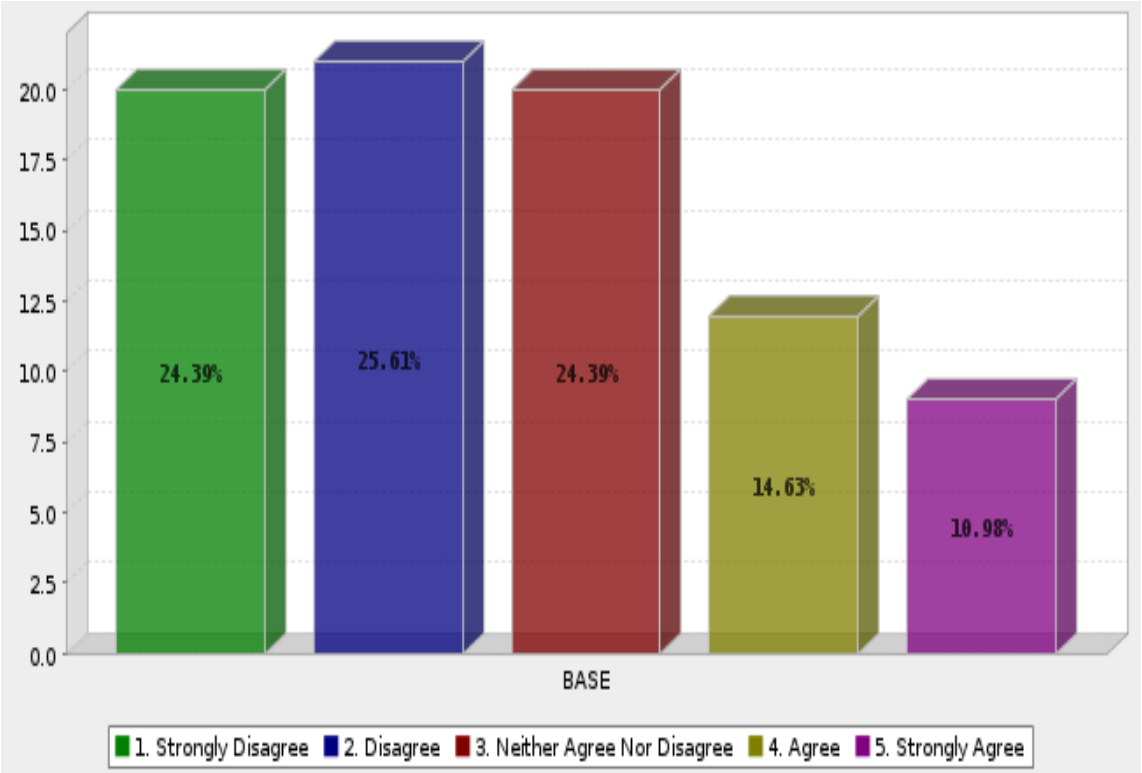


Figure 2.5.6
Percentage for Batch IVF

Figure 2.5.6 depicts Five-point Likert scale graphical representation is shown for intervention 'Batch IVF' as selected by survey respondents.

Table 2.5.6 Five-point Likert scale descriptive statistics is shown for 'Batch IVF' by survey respondents.

Table 2.5.6
Percentage for Batch IVF.

Answer	**Percent (%)**	**Count(N)**
Strongly Disagree	24%	20
Disagree	26%	21
Neither Agree nor Disagree	24%	20
Agree	15%	12
Strongly Agree	11%	9
Total	100%	82
Mean	2.62	
Confidence Interval @ 95%	[2.340 - 2.904]	
Standard Deviation	1.302	
Standard Error	0.144	

Figure 2.5.7 depicts Five-point Likert scale graphical representation is shown for intervention 'In-house diagnostics' as selected by survey respondents.

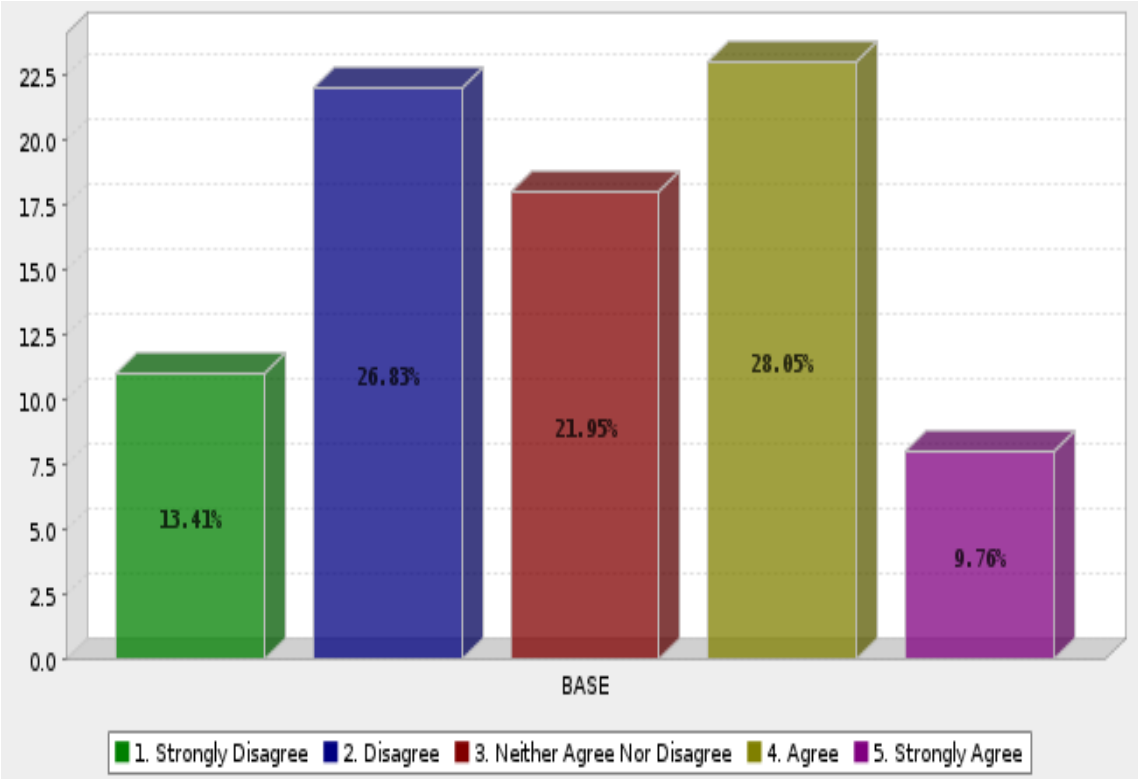


Figure 2.5.7
Percentage for in house Diagnostics

Table 2.5.7 Five-point Likert scale descriptive statistics is shown for 'In-house diagnostics' by survey respondents.

Table 2.5.7
Percentage for in house Diagnostics

Answer	**Percent (%)**	**Count(N)**
Strongly Disagree	13%	11
Disagree	27%	22
Neither Agree nor Disagree	22%	18
Agree	28%	23
Strongly Agree	10%	8
Total	100%	82

Mean	2.94
Confidence Interval @ 95%	[2.675 - 3.203]
Standard Deviation	1.221
Standard Error	0.135

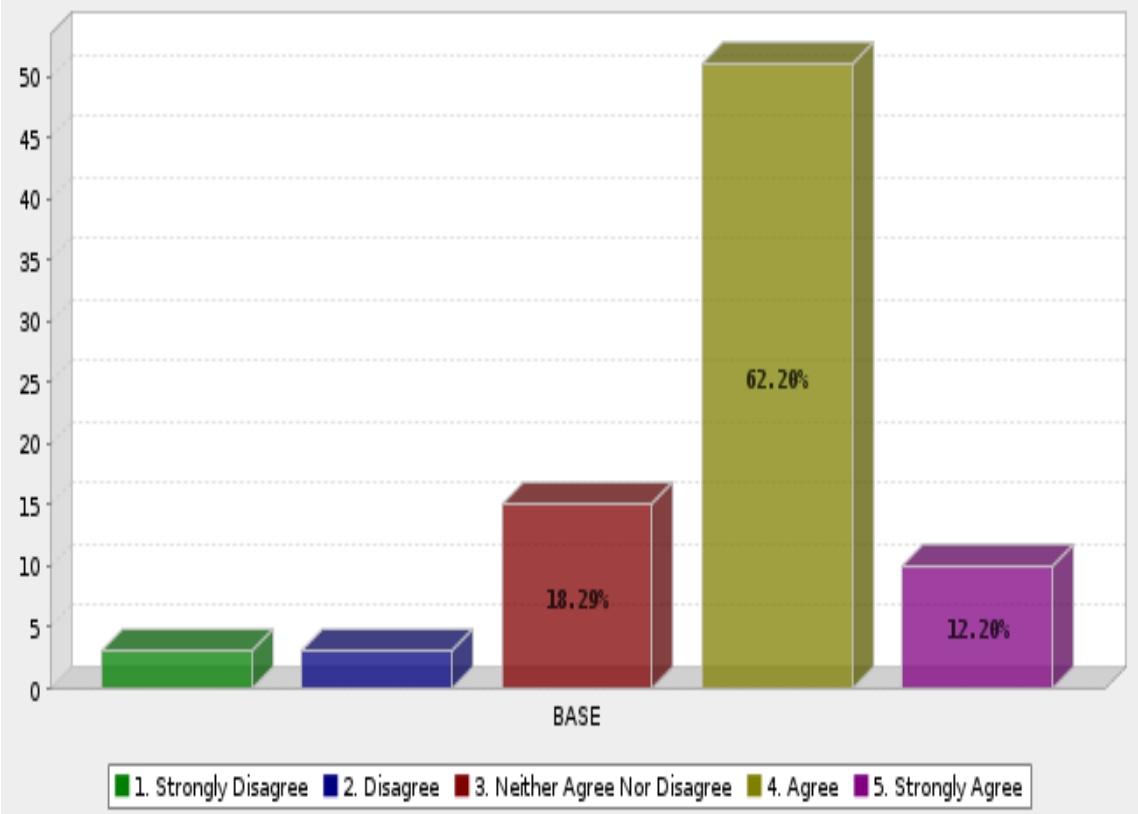


Figure 2.5.8
Percentage for Day3 vs. Day 5 embryo culture practices

Figure 2.5.8 depicts Five-point Likert scale graphical representation is shown for intervention 'Day3 vs. Day 5 embryo culture practices' as selected by survey respondents.

Table 2.5.8 Five-point Likert scale descriptive statistics is shown for ‘Day3 vs. Day 5 embryo culture’ by survey respondents.

Table 2.5.8
Percentage for Day3 vs. Day 5 embryo culture practices.

Answer	**Percent (%)**	**Count(N)**
Strongly Disagree	4%	3
Disagree	4%	3
Neither Agree nor Disagree	18%	15
Agree	62%	51
Strongly Agree	12%	10
Total	100%	82
Mean	3.76	
Confidence Interval @ 95%	[3.571 - 3.941]	
Standard Deviation	0.854	
Standard Error	0.094	

Figure 2.5.9 depicts Five-point Likert scale graphical representation is shown for intervention ‘Choosing Lower priced injectable (hMG vs. recombinant, biosimilars vs. original formulations)’ as selected by survey respondents.

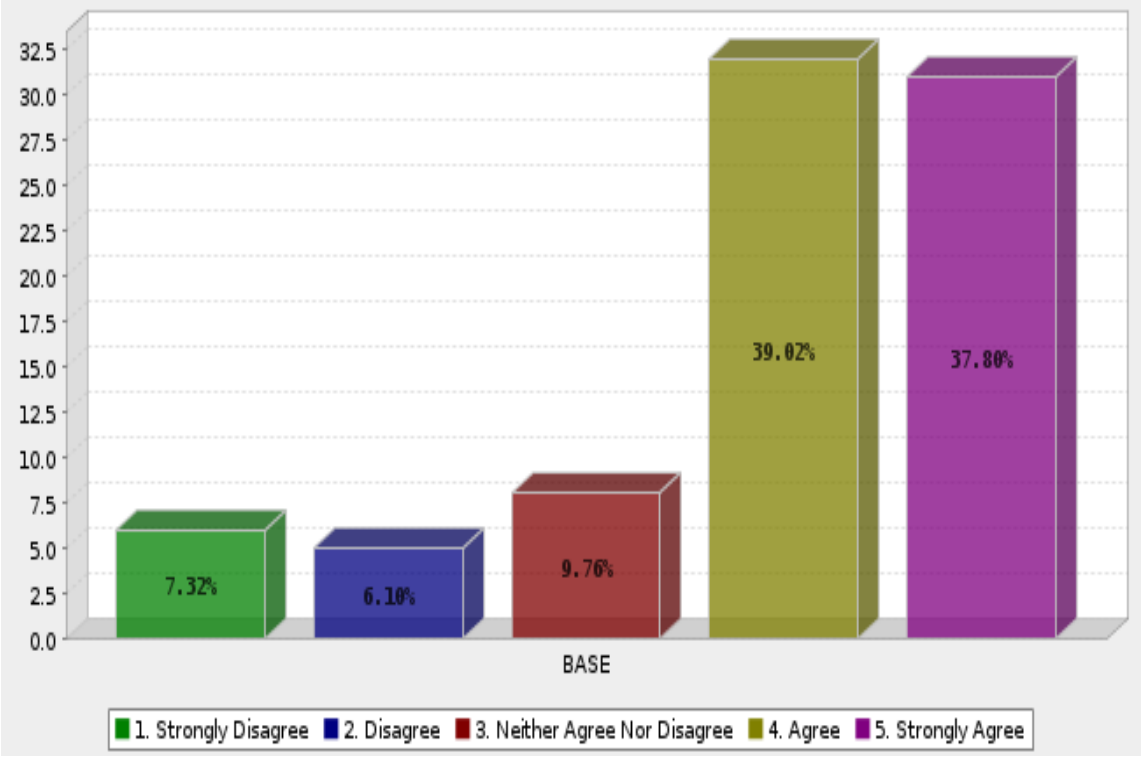


Figure 2.5.9
Percentage for Choosing Lower priced injectable.

Table 2.5.9 Five-point Likert scale descriptive statistics is shown for 'Choosing Lower priced injectable (hMG vs. recombinant, biosimilars vs. original formulations)' by survey respondents.

Table 2.5.9
Percentage for Choosing Lower priced injectable.

Answer	**Percent (%)**	**Count(N)**
Strongly Disagree	7%	6
Disagree	6%	5
Neither Agree nor Disagree	10%	8
Agree	39%	32
Strongly Agree	38%	31
Total	100%	82

Mean	3.94
Confidence Interval @ 95%	[3.684 - 4.194]
Standard Deviation	1.180
Standard Error	0.130

Figure 2.5.10 depicts Five-point Likert scale graphical representation is shown for intervention 'Bulk lab culture media vs. small packs (30 ml culture media vs. 10ml, Large Vitrification kits vs. small kits)' as selected by survey respondents.

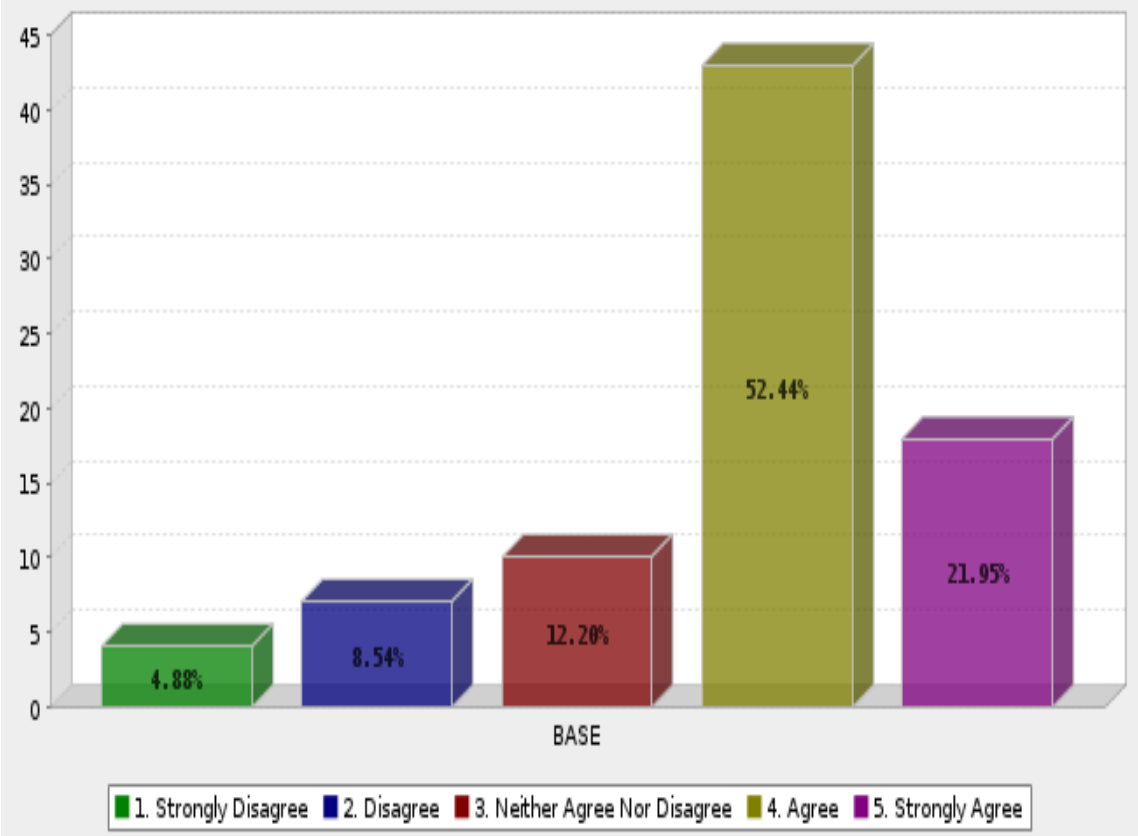


Figure 2.5.10
Percentage for Bulk lab culture media vs. small packs.

Table 2.5.10 Five-point Likert scale descriptive statistics is shown for ‘Bulk lab culture media vs. small packs (30 ml culture media vs. 10ml, Large Vitrification kits vs. small kits)’ by survey respondents.

Table 2.5.10
Percentage for Bulk lab culture media vs. small packs.

Answer	**Percent (%)**	**Count(N)**
Strongly Disagree	5%	4
Disagree	9%	7
Neither Agree nor Disagree	12%	10
Agree	52%	43
Strongly Agree	22%	18
Total	100%	82
Mean	3.78	
Confidence Interval @ 95%	[3.555 - 4.006]	
Standard Deviation	1.043	
Standard Error	0.115	

4.8 Summary of Findings

Survey responses have been compared in a detailed discussion with the Mock calculations with a Panel of experts which includes the author who is a CXO /senior management professional with 20 years of corporate & entrepreneurship experience out of which his last 12 years of experience in Fertility and multispecialty hospital as CEO, a senior Reproductive Specialist with 33 years of experience in the field , a senior Clinical Embryologist and CEO of a Fertility focused think tank having 12 years of experience and inputs and pricing obtained from industry professionals who are either distributors or manufacturers in this field for more than two decades.

Summaries of all cost saving interventions have been made from detailed calculations vs. survey results below;

Projected Savings Rs 240 for keeping minimal inventory.

Survey Results: Rs 7414.63 per procedure.

The survey respondents have grossly overestimated savings from keeping minimal inventory.

Projected Savings: Rs 9390 per procedure using minimal stimulation practices.

In this case projected savings is similar to actual and in fact 'underestimated' by Survey respondents by about 100% if Vendor 1 is used.

Projected Savings = Rs 12000 by elective freezing.

Survey Results = Rs 10050.

The respondents have slightly underestimated the savings by elective freezing in cycles per patients vs. freeze all. Projected savings are very high for patients with low

ovarian reserve with mild stimulation cycle allowing for fresh embryo transfer. This could enable IVF units to provide the same level of care and pregnancy rates to these low prognosis patients at a more effective cost and allowing them to undergo multiple cycles of embryo transfer which they quite frequently require.

Projected Savings for elective ICSI procedures: Rs 3200.

Survey Results: Rs 9634 Rs per procedure.

Survey respondents have overestimated the savings of using ICSI for only indicated cases. Actual savings are approximately 3200 Rs per patient per case, while respondents have estimated approximately Rs 9650 saved.

ICSI use should be determined only by need in spite of the same as ICSI is an invasive procedure with its own estimated risks. However, considering the advances in performing ICSI and high level of technical training now available to embryologists, the risks associated with ICSI are minimal in well maintained Fertility units.

Survey Results: Rs 8257/-.

Projected Savings for Overhead expenses: Custom to each unit.

Dependant on employee experience and number Savings favor moderately experienced staff with very experienced management consultants to drive the Fertility Unit. Clinical costs cannot be reduced as it is central to providing good medical care.

Projected Savings for Batch IVF: Minimal to Nil.

Survey Results: 8910 Rs /- per patient.

Survey results have highly overestimated the cost saving achieved with the Batch IVF.

This has been summarized in discussion and the rationale provided is there is no method of saving cost with Batch IVF without reducing per patient pregnancy rate as well as no effective methodology of reducing errors with increased patient load which is likely to be a medico-legal disaster in the making. Hence the panel of experts has theorized ‘Batch IVF should not be practiced unless there is a lacuna of medical experts in the field in a geographical location or in cases of emergency.

Projected Savings for In House Diagnostics: Rs 5000/-.

Survey Results: Rs 7134/-.

In House Diagnostics can save a significant amount per annum for a Fertility unit.

The average cost saving that the survey associated with the intervention is 7134 Rs per patient which is only slightly higher than actual savings. Actual savings may also vary as per the salary requirements per geographical location as India is diverse in terms of labor costs.

The survey evaluated fairly well and rated In House Diagnostics high on the list of associated savings per patient if investment is made to incorporate the same. As with all interventions initial capital costs are not part of the review.

Projected Savings for Day 3 vs. Day 5 Culture practices: Nil or minimal.

Survey Results: Rs 7940/-.

The survey has overestimated savings for Day 3 vs. Day 5 embryo culture. Decision for shortened vs. extended culture should be medically driven and there is no difference for well-maintained IVF Laboratories between the two methodologies.

Projected Savings: Rs 22500 Rs per procedure.

Survey Results: Rs 14250 per procedure.

In this case projected savings are 'underestimated' by Survey respondents by about Rs 8000-10000 Rs if lowered priced gonadotropins are used.

Projected Savings: Rs 700/- per procedure for bulk media vs. small packs.

Survey Results: Rs 8200/-.

The savings are highly overestimated for use of bulk use media by the respondents. Although certain modest savings are seen, but there is no reason to change internal practices or media for cost saving purposes. In fact, if the number of patients for vitrification isn't sufficient in the given time frame, the risk of contamination or osmolality change is high during use of bulk media which can adversely affect the ivf treatment cycle final results. Also bulk media needs to be allocation i.e. dividing the bulk media pack into smaller packs which may increase the chances of pilferages and wastage of the not only the media but also increasing the man hours of the embryologist, this waste & additional man ours cost may negate the cost saving done on opting for bulk media packs.

The survey results vs. the calculated savings have been tabulated below in the Table 2.6 for understanding and arranged according to calculated savings for the sake of ranking.

Table 2.6
Survey results vs. the calculated savings

S. N	Title	Survey Results {Survey) (in Rs per procedure)	Calculated Savings (in Rs per procedure)	Difference (Survey – Calc in Rs per procedure)	Over or Under Estimation
1	Keeping limited inventory (IVF drugs & lab consumables)	7,420	240	7180	Overestimation
2	Using minimal stimulation practices	9,400	20000	-10600	Underestimated
3	Elective freezing (no Freeze All)	10,050	12000	-1950	Underestimated
4	ICSI only for moderate and severe male infertility	9,640	3200	6420	Overestimation
5	Reducing overhead expenses (management, accountancy, reception etc.)	8,260	Custom	Not Calculated	Not Calculated

6	Batch IVF	8,900	Nil / Minimal	8900	Overestimation
7	In-house diagnostics	7,140	5000	2140	Overestimation
8	Day3 vs. Day 5 embryo culture practices	7,940	Nil / Minimal	7940	Overestimation
9	Choosing Lower priced injectable (hMG vs. recombinant, biosimilars vs. original formulations)	14,250	22500	-8250	Underestimation
10	Bulk lab culture media vs. Small packs (30 ml culture media vs. 10ml, Large Vitrification kits vs. small kits)	8,200	700	7500	Overestimation

Below Figure 2.6 contains the ranking as given by survey respondents' vs. the calculated savings rankings as per the discussions and the panel of experts.

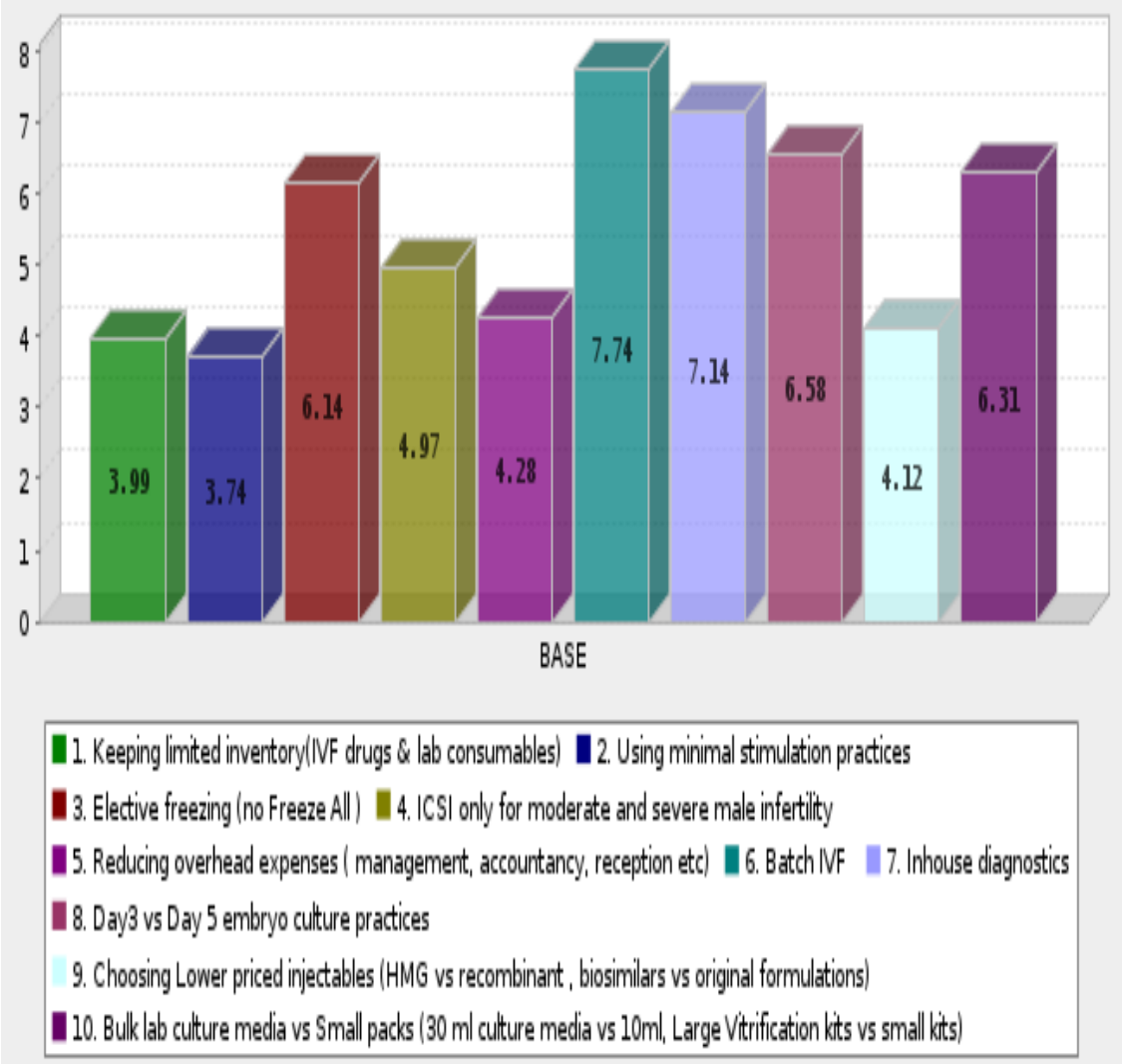


Figure 2.6
Average ranking score by survey respondants.

Table 2.7 below displays the comparative table of survey ranking vs calculated savings rankings .

Table 2.7
Survey Results Ranking of Interventions.

Sr No.	Particulars	Survey Ranking	Calculated Savings Ranking
1	Keeping limited inventory (IVF Drugs & Lab consumables)	1	8
2	Using minimal stimulation practices	2	2
3	Elective freezing (no freeze all)	3	3
4	ICSI only for moderate and severe male infertility	4	5
5	Reducing overhead expenses (Management, Accountancy, reception etc.)	5	7
6	Batch IVF	6	10
7	In-house diagnostics	7	4
8	Day3 vs. Day 5 embryo culture practices	8	9
9	Choosing Lower priced injectable (hMG vs. Recombinant, Biosimilars vs. original formulation)	9	1
10	Bulk lab culture media vs. small packs (culture media 30 ml vs. 10 ml, large vitrification kits vs. small kits)	10	6

CHAPTER V:

DISCUSSION

5.1 Discussion of Results

Table 3.1 provides the List of Interventions for Cost optimization .

Table 3.1
Interventions for cost optimisation.

Particulars
1. Keeping limited inventory (IVF Drugs & Lab consumables)
2. Using minimal stimulation practices
3. Elective freezing (no freeze all)
4. ICSI only for moderate and severe male infertility
5. Reducing overhead expenses (Management, Accountancy, reception etc.)
6. Batch IVF
7. In-house diagnostics
8. Day3 vs. Day 5 embryo culture practices
9. Choosing Lower priced injectable (hMG vs. Recombinant, Biosimilars vs. original formulation)
10. Bulk lab culture media vs. small packs (culture media 30 ml vs. 10 ml, large vitrification kits vs. small kits)

5.1.1 Keeping limited inventory (IVF Drugs & Lab consumables)

Mock IVF #1: Average 50 Cycles per month.

Average savings as per procedure for Stockless systems have been shown to reduce inventories by 70% -80%, and reduce staff full time equivalents (FTEs) by 30%-45%.

In India in most units however, material handler costs are divided or a person in the role of nurse or front desk is responsible for the same and the FTE reductions are minimal.

Example - 2 Handlers / Front office personnel = Rs 30000 per month; FTEs of 40% reduction, translates to 12000 Rs saving in man hours which may not be translated in reduced staff by hospital. Rs 12 k per month for an IVF Unit performing 50 IVF cycles and miscellaneous 100 procedures all inclusive (sonograms, IUIs, HSGs, etc.) translates to 80 Rs saved per procedure in FTEs (12000 / (50+100)) = 80).

In terms of inventory wastage, most gonadotropins and consumables are of long expiry of one to two years and do not translate into savings to a unit.

Low expiry culture media is the most affected consumable in IVF and often follows the ‘Stockless’ approach where limited quantity for the month is ordered in Fertility units, however, considering an average of 20% inventory wastage on large stockages. We approximate on average 40 ml out of 200 ml is wasted per month Averaging a saving of 40 ml worth of culture media on average for 50 IVF Cycles, 40 x *200 Rs per ml(higher average) = Rs 8000 for 50 cycles. Per Procedure savings = 160 Rs

Total Savings per procedure: Rs 240 for keeping minimal inventory.

Projected Savings: Rs 7414.63 per procedure.

The survey respondents have grossly overestimated savings from keeping minimal inventory.

5.1.2 Using minimal stimulation practices

The practice of ovarian stimulation for IVF is undergoing a fundamental re-evaluation as recent data begin to successfully challenge the traditional paradigm that ovarian stimulation should be aimed at the retrieval of as many oocytes as possible, in the belief that this will increase pregnancy rates. An opposing view is that live birth rate should not be the only endpoint in evaluating the success of IVF treatment and that equal emphasis should be placed on safety and affordability.

The International Society for Mild Approaches in Assisted Reproduction (ISMAAR) committee has carried out an up-to-date literature search, with the evidence being graded according to the University of Oxford's Center for Evidence-Based Medicine. The recommendations were formulated taking into account the quality of evidence on the efficacy, risk and cost of each intervention. ISMAAR recommends adopting a mild approach to ovarian stimulation in all clinical settings as an increasing body of evidence suggests that mild stimulation is as effective as conventional stimulation, while being safer and less expensive.

Minimal ovarian stimulation IVF(MS-IVF), in which lower doses of hormones are taken for a shorter duration, has become increasingly popular because it has been

found to create a more natural physiological response(i.e., a hormonal milieu more similar to a natural cycle), with lower levels of discomfort and costs. Lower levels of discomfort may prevent dropouts, whereas lower costs may allow patients to undergo more treatment cycles for the same amount of money. (Oudshoorn et al. 2019)

To determine cost effectiveness of Mini Stimulation IVF (MS-IVF) compared to Conventional IVF (C-IVF) we have to compare cost of gonadotropins consumed.

The total dosage of hMG required for ovarian stimulation was significantly lower in the MS-IVF treatment protocol. Ranges: Mild IVF 1000-1200 IU reduction, while Micro IVF 1500-1800 IU reduction.

Considering Micro-IVF has low popularity in India, assuming Mild IVF use.

Per patient approximately 1000-1200 IU is projected to be saved in injectable while approximately 3000 Rs added in pills (Clomiphene Citrate / Letrozole).

As per calculations, per unit cost of a recombinant FSH or hMG of renowned brands like Merck(Gonal F) , Ferring(Menopur) is approximately between 15-20 Rs per IU for highly purified hMG or patented biomolecules known as ‘Vendor 1’vs 5-10 rs per IU for local brands known as ‘Vendor 2’.

If Vendor 1 is used approximate savings range up to: 15000 Rs to 24000 Rs per procedure / cycle, Vs. Vendor 2 approximate savings range from 5000-12000 Rs per procedure / cycle.

Project Saving Rs 5000 to 24000.

Survery result Rs 9390.

Many IVF Units in India use a mix of recombinant and urinary gonadotropins so actual cost saving average within the range of 5000-24000 dependent on individual centers.

In this case projected savings is similar to actual, and it has been ‘underestimated’ by Survey respondents by about 100% if Vendor 1 is used.

5.1.3 Elective freezing (no freeze-all)

Considering that all patients undergo a substantial dosage of injectable gonadotropins and hormones during the ovarian stimulation, the endometrium is exposed to high amounts of progesterone and estrogen making it less conducive to resultant implantation. After advent of process of vitrification in embryology, the entire fraternity gets 99% -100% retrieval of frozen embryos, making freezing all cycles very common. It is now uncommon to see clinicians abandon the same for elective freezing.

This was the case until 2021. However, after ART Bill was introduced, the access to donor oocytes has reduced drastically, increasing the number of self-gametes used in IVF. Due to lowered ovarian reserve, these patients who would have been candidates for oocyte donation are undergoing multiple rounds of self-cycles reducing the number of available oocytes and also making mild IVF popular again in practice, hence elective freezing could make a comeback in Indian fertility services scenario.

The potential of fresh embryo transfer for low reserve patients with limited oocyte can reduce the cost per cycle as below.

Cost of vitrification + thawing + (up to 2) cryo devices + endometrial preparation + hormonal injectable / pills = 5000 +5000 +5000+ 5000 + 5000 = 35000 Costs for IVF Unit.

For a patient with multiple embryos / blastocysts the cost saving would range in saving 1 cryo device use. 1 less endometrial preparation + hormonal pills / injectable.

Cost saving = 2000+5000+5000 = 12000 Costs for IVF unit.

Projected Savings = Rs 12000-35000 by elective freezing.

Survey Results = Rs 10050/-.

The respondents have underestimated the savings by elective freezing in cycles per patients vs. freeze all.

Projected savings are very high for patients with low ovarian reserve with mild stimulation cycle allowing for fresh embryo transfer. This could enable IVF units to provide the same level of care and pregnancy rates to these low prognosis patients at a more effective/affordable cost and allowing them to undergo multiple cycles of embryo transfer which they quite frequently require to improve the pregnancy rate chances for low prognosis patients.

5.1.4 ICSI only for moderate and severe male infertility

Cost Saving Calculated by current ICSI usage 90% of cases to required ICSI usage 30% of cases.

Moving to about 1/3rd case load. Total case load in survey Is 43 (forty three) cycles per month average.

Based on incidence of true male infertility and combined factor cases is 30% of overall case load on average.

ICSI utilization shifts to Conventional IVF and goes from 9/10th to 3/10th, reduction of total cost calculation below;

ICSI use in all cases vs. ICSI use only in 30% cases = cost saving of (13220-10336) per case = 3183/-.

= per month 3183*avg 22 cases =70024 Rs per month = 70024 Rs *12 per annum = 840293 Rs per annum.

Projected Savings for elective ICSI procedures: Rs 3200/-.

Survey Results: Rs 9634 Rs per procedure.

Survey respondents have overestimated the savings of using ICSI for only indicated cases. Actual savings are approximately 3200 Rs per patient per case, while respondents have estimated approximately Rs 9650 saved.

ICSI use should be determined only by need in spite of the same as ICSI is an invasive procedure with its own estimated risks. However, considering the advances in

performing ICSI and high level of technical training now available to embryologists, the risks associated with ICSI are minimal in well maintained Fertility units.

5.1.5 Reducing overhead expenses (Management, Accountancy, reception etc.)

Overhead expenses are normally the cost of running a unit. These costs are divided between different departments in a Gynecology and Fertility setup and are only dedicated in niche tertiary care Fertility units.

Projected Savings from Survey: Rs 8257/-.

Such saving calculations would be approximately dependent on the organizational structure of a Fertility Unit.

Overhead expenses mainly arise from employee salaries and management personnel who are the highest paying in most fields. As Fertility is a small hospital-based unit, it is possible to reduce overhead expenses by ensuring regular audits and consultations are conducted by senior management professional as well as senior industry professionals for staying on top of industry and medical practices. It is frequently unnecessary to employ highly paid managers full time for small hospitals and as such the expenses should be shared in a ‘group of practitioners’ within a certain geographical scope to allow for efficient organizational efficiency.

It is not possible to calculate such savings from Mock examples and survey response will be considered adequate for the scope of this thesis.

5.1.6 Batch IVF

Batch IVF is a practice known in the fertility units in India. Primarily it entails collecting the patient procedures together on certain days in a month to allow for;

a) Trained experts hiring for improved outcomes.
b) Limited days of laboratory maintenance to reduce cost.
c) Optimized utilization of low shelf-life specialty cell culture media to reduce costs.
d) Allowing for patient procedure streamlining on the same timeline for improving efficiency.

Effective utilization of same has been practiced for decades with efficiency in many State-of-ART Fertility units in India and most single standing or corporate chains have practiced Batch IVF at some point in their clinical practices.

Cost Saving calculation for a Center conducting batch is a little more complex than other interventions as it depends on the individual circumstances and reasons for the practice in case of lack of expertise; cost calculation is an irrelevant approach.

In case of limited days of maintenance.

For Example - In a Basic Embryology laboratory.

Embryology laboratory working 1 week a month vs. 25 days a month.

Cost of electricity for a 5 KVA Basic Laboratory setup = 80 units per day.

So, the difference is 2400 units vs. 600 units per month can be up to 25000 Rs per month with average cost of Rs 15 per unit.

Cost of gases required for running 2 Incubators =

Gas bills can be added to the laboratory. Mixed gases are more expensive and require frequent usage if the incubators are consistently opened (during batch) and also when opened over a period of time (regular clinical load).

Gas use can be reduced in batch work to following Mixed gas can be extended for use up to 4 times as batch work usually lasts a week vs. a month for regular workload.

In cost the charges per annum can vary from 50000 for per annum regular load vs. 12500 Rs for batch work.

Cost of Annual maintenance is same.

Cost of staff is same as staff is normally full time in most setups.

Projected Savings for Batch IVF: Minimal to Nil.

Survey Results: 8910 Rs /- per patient.

Survey results have highly overestimated the cost saving achieved with Batch IVF. However, a strong point to be considered apart from cost is batch work can increase potential errors due to high processing load of patients and over filling of incubators as well as exhaustion of lab and clinical personnel.

The final cost of errors would be far higher than any savings that result. If these factors are taken care of, which entails relaxing the batch days, increasing staff personnel and keeping adequate clinical gaps to allow for rest of staff, the cost implications will be deemed to be only minor reduction as Batch work would need more resources in short period of time.

5.1.7 In House Diagnostics

In house diagnostics especially for tests that are frequently done in Fertility testing and evaluation could ease the load on patients as well as reduce the turnaround time for testing depending on the circumstances and availability of diagnostic laboratories providing competent services.

In a Mock example let's compare the cost saving projected by the survey respondents with calculated savings.

In a center performing 50 cycles per month, on an average let's consider a minimum of 50 testing of below hormones and diagnostics. Among these the ones that are primarily insourced are hormonal and biochemical analyses.

Female

a) FSH, LH, Estradiol β, Progesterone, Prolactin, AMH.
b) Extended testing: Vitamin D.

Male

a) Testosterone, Estradiol β.
b) Extended testing: Vitamin D.
c) Semen Analysis.
d) Sperm DNA Fragmentation.

The pricing from NABL accredited laboratories is compared to in-house diagnostic testing below for the above tests.

Table 3.1.1
Diagnostic test comparison cost

Test	External Lab (in Rs)	Internal Lab (in Rs)
FSH	400	200
LH	400	200
Estradiol β	500	250
Progesterone	500	250
Prolactin	400	200
AMH	1200	600
Vitamin D	1200	400
Testosterone	400	200
Semen Analysis	1000	300
Sperm DNA Fragmentation	4000	2400
Total	10000	5000

Projected Savings for In House Diagnostics: Rs 5000/-.

Survey Results: Rs 7134/-.

Average saving per month for 50 cycles: 2,50,000/- per month.

Maintenance and employee cost charges of equipment & testing kits per month in diagnostic lab: Rs 1,60,000/- per month.

Cost saving per annum = Rs. 30,00,000 – Rs. 19,20,000 = Rs.1080000/- per annum.

Translate to Rs 90000/- per month (Rs 1080000 / 12).

Thus Rs 90000 / 50 cycles = Rs 1800/- per cycle is net profit

In House Diagnostics can save a significant amount per annum for a Fertility unit. The average cost saving that the survey associated with the intervention is 7134 Rs per patient which is only quite higher than actual savings. Actual savings may also vary as

per the salary requirements per geographical location as India is diverse in terms of labor costs, rentals etc.

The survey evaluated fairly well and rated In House Diagnostics high on the list of associated savings per patient if investment is made to incorporate the same. As with all interventions initial capital costs & loss due to breakdown of the machinery & equipments are not part of the review.

5.1.8 Day3 vs. Day 5 embryo culture practices

The primary difference between Day 3 and Day 5 embryo culture is the need for a VOC (volatile organic compounds) maintained environment having very little VOCs (volatile organic compounds) to allow for extended culture to blastocyst formation successfully (VOC - volatile organic compounds can affect the embryo formation, higher volatile organic compounds will hamper the growth & degenerate the human gametes thus pharmaceutical grade air filtration system is required to maintain the air quality conducive for embryo growth). If an already optimized IVF laboratory shifts to Day 3 culture the cost savings associated may be due to multiple factors.

a) Availability of Senior Embryologists for the case as India suffers from a huge lack of expertise in Embryology. However, the lacuna is being rapidly filled by highly trained and skilled embryologists graduating from university recognized courses in Clinical Embryology.

b) The ability to terminate culture earlier allowing for lower space requirements per patient in the laboratory for busy laboratories.

c) The reduction in need of change of culture dishes and consumables required for the procedure.

d) Day 3 culture may also increase costs due to higher usage of cryopreservation consumables

Table 3.1.2
Average cost for either Day 3 vs. Day 5.

Process	Day 3 Cleavage Stage Culture	Day 5/6 Extended Culture
Oocyte Retrieval	Same	Same
Intra Cytoplasmic Sperm Injection	Same	Same
Embryo Culture till Day 3	Same	Same
Day 3- Day 5	None	5000 Rs
Vitrification Costs (up to 5 Day 3 Emb or 3 Blastocysts)	8000-10000 Rs	5000-6000 Rs

Survey Response: Rs 7940/- per procedure.

Day 3 Culture vs. Day 5 culture cancel out approximately due to higher costs of vitrification with Day 3 vs. similar increase in embryo culture cost for Day 5 hence, keeping culture decision as per medical requirements is the best course of action and does not change the cost parameters for the Fertility unit.

5.1.9 Choosing Lower priced injectable (hMG vs. Recombinant, Biosimilars vs. original formulation)

The total dosage of hMG required for controlled ovarian stimulation for an average responder with average days of stimulation will be used for cost calculations between differently priced injectable.

Low-Cost Pricing with Biosimilars.

Total hMG Dosage.

Recombinant FSH Dose 300 IU for 10 Days is comparable to urinary hMG 450 doses clinically.

Sometime recombinant FSH and LH is in single vial by one company. Due to low volumes in the market and use in specific clinical indications this has not been added to the comparison.

Per Unit Cost of a recombinant FSH or hMG of renowned brands like Merck (Gonal F), Ferring (Menopur) is approximately between 15-20 Rs per IU for highly purified hMG or patented biomolecules known as 'Vendor 1'vs 5-10 rs per IU for local brands known as 'Vendor 2'.

Calculations Vendor 1 = 15 Rs per Unit * 300 units *10 days = Rs 45000/-.

Calculations Vendor 2 = 5 Rs per Unit*450 *10 days = Rs 22500/-.

Table 3.1.3
Price per patient stimulation & saving.

	Pricing per patient stimulation	Savings
Vendor 1	Rs 45000/-	-
Vendor 2	Rs 22500/-	Rs 22500/-

Projected Savings: Rs 22500 Rs per procedure.

Survey Results: Rs 14250 per procedure.

In this case projected savings are 'underestimated.' by Survey respondents by about Rs 8000-10000 Rs if lowered priced gonadotropins are used.

5.1.10 Bulk lab culture media vs. small packs (culture media 30 ml vs. 10 ml, Large vitrification kits vs. small kits)

In the vitrification procedure, there is a cost associated with the specialized cell freezing media required. There have been certain providers in the market that create bulk volume media and claim per patient reduction in costs associated with the same.

Cost saving calculation.

Vendor 1: Small Size packs up to 2 ml.

Vendor 2: Bulk Size packs up to 10 ml.

Vendor1: 10000 Rs for 2 ml, up to 6 patients' usage; 1670 Rs per patient.

Vendor2: 30000 Rs for 10 ml up to 30 patients' usage: 1000 Rs per patient.

Cost Saving per procedure /patient.

Vendor 2 vs. Vendor 1 cost saving = 1670 Rs -1000 Rs 670 Rs per patient.

Projected Savings: Rs 700/- per procedure for bulk media vs. small packs.

Survey Results.

Savings are highly overestimated for use of bulk use media. Although certain modest savings are seen, there is no reason to change internal practices or media for cost saving purposes. In fact, if numbers of patients for vitrification aren’t sufficient in the given time frame, the risk of contamination or osmolality change is high during use of bulk media.

5.2 Discussion of Research Question One

Research Question 1 – What are the key factors contributing to Cost of Fertility/IVF treatment in India and how to make IVF treatment more affordable?

From the survey generated results and from the Mock IVF Projected Savings calculations performed to look at the basic ten parameters that can have impact on cost saving of Fertility focused Single Speciality hospitals, the main parameters ranked as per the survey are as below.

The survey results vs. the calculated savings have been tabulated below in the Table 3.2 for understanding and arranged according to calculated savings for the sake of ranking.

Table 3.2
Survey results vs. the calculated savings.

Sr. No	Title	Survey Results {Survey) (in Rs per procedure)	Calculated Savings {Calc) (in Rs per procedure)	Difference (Survey – Calc in Rs per procedure)	Over or Under Estimation
1	Keeping limited inventory (IVF drugs & lab consumables)	7,420	240	7180	Overestimation
2	Using minimal stimulation practices	9,400	20000	-10600	Underestimated

3	Elective freezing (no Freeze All)	10,050	12000	-1950	Underestimated
4	ICSI only for moderate and severe male infertility	9,640	3200	6420	Overestimation
5	Reducing overhead expenses (management, accountancy, reception etc.)	8,260	Custom	Not Calculated	Not Calculated
6	Batch IVF	8,900	Nil / Minimal	8900	Overestimation
7	In-house diagnostics	7,140	5000	2140	Overestimation
8	Day3 vs. Day 5 embryo culture practices	7,940	Nil / Minimal	7940	Overestimation
9	Choosing Lower priced injectable (hMG vs. recombinant, biosimilars vs. original formulations)	14,250	22500	-8250	Underestimation

10	Bulk lab culture media vs. Small packs(30 ml culture media vs. 10ml, Large Vitrification kits vs. small kits)	8,200	700	7500	Overestimation

The below Figure 3.1 contains the graph ranking as given by survey respondents' vs. the calculated savings rankings as per the discussions and the panel of experts.

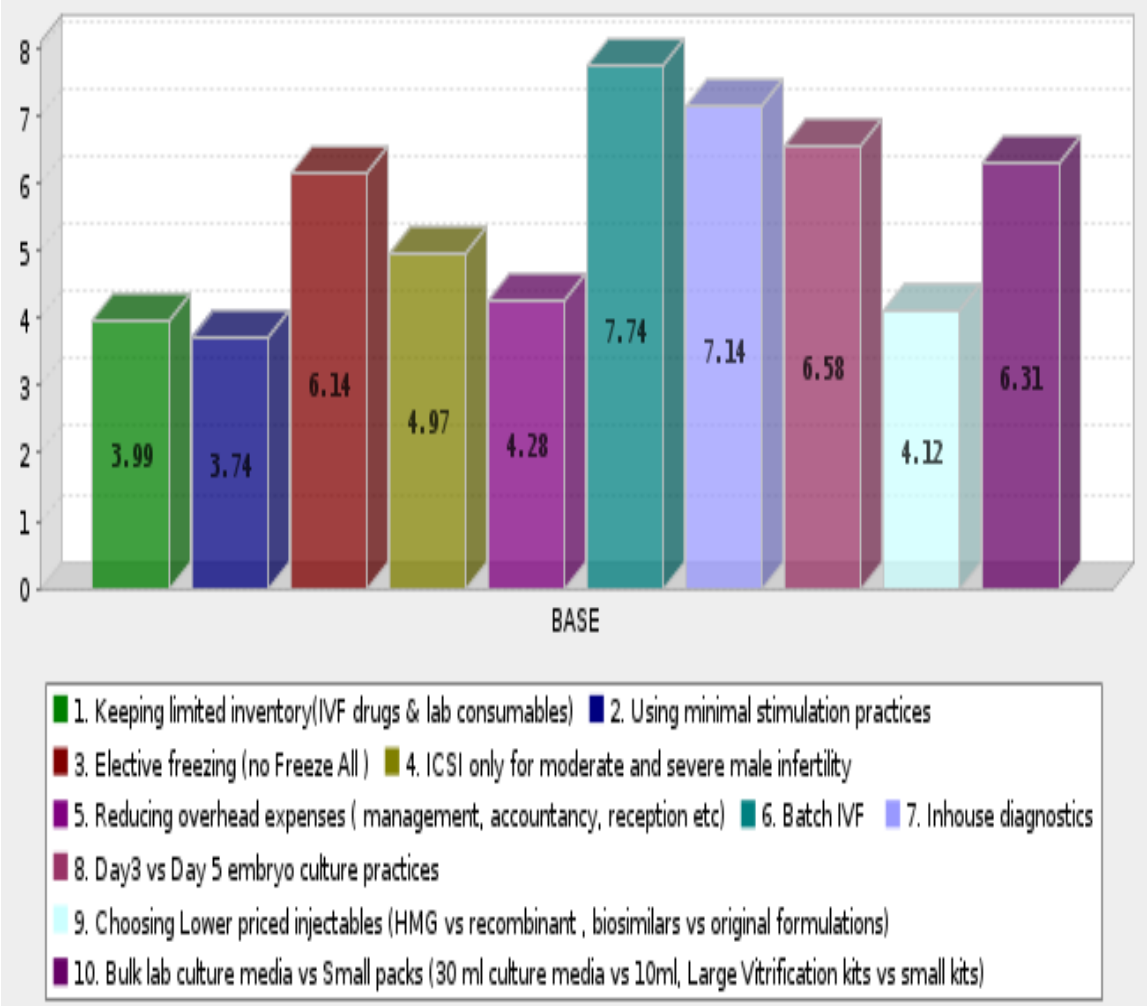


Figure 3.1
Survey Results Ranking of Interventions

Table 3.2.1
Survey results of ranking interventions

Sr No.	Particulars	Survey Ranking	Calculated Savings Ranking
1	Keeping limited inventory (IVF Drugs & Lab consumables)	1	8
2	Using minimal stimulation practices	2	2
3	Elective freezing (no freeze all)	3	3
4	ICSI only for moderate and severe male infertility	4	5
5	Reducing overhead expenses (Management, Accountancy, reception etc.)	5	7
6	Batch IVF	6	10
7	In-house diagnostics	7	4
8	Day3 vs. Day 5 embryo culture practices	8	9
9	Choosing Lower priced injectable hMG vs. Recombinant, Biosimilars vs. original formulation)	9	1
10	Bulk lab culture media vs. small packs (culture media 30 ml vs. 10 ml, large vitrification kits vs. small kits)	10	6

There is a huge difference as seen above between what Fertility stakeholders believe and calculated cost savings based on the identified parameters.

Improving access to care of IVF is dependent on the ground level management personnel and clinical coordinators and decision makers in the industry. As a huge lacuna in understanding of cost parameters is identified and demonstrated in the survey, first off, a national level scale up of Auditing and management services regarding financial prudence and cost saving is required in the field.

India is projected to do 3.5 lakh IVF cycles per annum by 2025 as per market reports at a CAGR of 9-10%. Such steady growth coupled with increased competition to IVF units has already unleashed a price and services war in the sector.

Either differentiation via strong clinical and management pipelines in multidisciplinary allied domains with Fertility or Fertility focused price sensitive effective service deployment are the two paths left for Fertility centers to pursue.

Considering the majority centers who are corporate driven can infuse more funds in advertising vs. single players, Single IVF unit players shall have to depend on their internal strengths while improving their financial management backbone which is currently severely lacking in the sector for Single or multiple doctor driven Fertility entities.

Market penetration improvement is currently underway and shall be augmented with focused service provision to Fertility industry in Cost Optimization Strategies.

Price is going to be a stringent factor going ahead for growth in IVF and Fertility units shall find this thesis a beginning primer in understanding how to current financial optimization can be approached.

5.3 Discussion of Research Question Two

Research Question 2 - What cost optimization methods will have the largest impact and which are feasible for implementation by ranking them for IVF Centers?

The survey results vs. the calculated savings have been tabulated below in the Table 3.3 for understanding and arranged according to calculated savings for the sake of ranking.

Table 3.3
Survey results vs. the calculated savings.

Sr. No	Title	Survey Results {Survey) (in Rs per procedure)	Calculated Savings {Calc) (in Rs per procedure)	Difference (Survey – Calc in Rs per procedure)	Over or Under Estimation
1	Keeping limited inventory (IVF drugs & lab consumables)	7,420	240	7180	Overestimation
2	Using minimal stimulation practices	9,400	20000	-10600	Underestimated
3	Elective freezing (no Freeze All)	10,050	12000	-1950	Underestimated

4	ICSI only for moderate and severe male infertility	9,640	3200	6420	Overestimation
5	Reducing overhead expenses (management, accountancy, reception etc.)	8,260	Custom	Not Calculated	Not Calculated
6	Batch IVF	8,900	Nil / Minimal	8900	Overestimation
7	In-house diagnostics	7,140	5000	2140	Overestimation
8	Day3 vs. Day 5 embryo culture practices	7,940	Nil / Minimal	7940	Overestimation
9	Choosing Lower priced injectable (hMG vs. recombinant, biosimilars vs. original formulations)	14,250	22500	-8250	Underestimation

10	Bulk lab culture media vs. small packs (30 ml culture media vs. 10ml, Large Vitrification kits vs. small kits)	8,200	700	7500	Overestimation

Below Table 3.3.1 contains survey respondents' vs. the calculated savings rankings for each intervention.

Table 3.3.1
Survey Results Ranking of Interventions.

Sr No.	Particulars	Survey Ranking	Calculated Savings Ranking
1	Keeping limited inventory (IVF Drugs & Lab consumables)	1	8
2	Using minimal stimulation practices	2	2
3	Elective freezing (no freeze all)	3	3
4	ICSI only for moderate and severe male infertility	4	5
5	Reducing overhead expenses (Management, Accountancy, reception etc.)	5	7
6	Batch IVF	6	10
7	In-house diagnostics	7	4

8	Day3 vs. Day 5 embryo culture practices	8	9
9	Choosing Lower priced injectable(hMG vs. Recombinant, Biosimilars vs. original formulation)	9	1
10	Bulk lab culture media vs. small packs (culture media 30 ml vs. 10 ml, large vitrification kits vs. small kits)	10	6

The Calculated Cost Saving Rankings are widely different than the Survey respondents and a gap in understanding is identified in Fertility stakeholders considering the financial implications of various interventions on Fertility practice.

Following the discussion in this thesis a Cost optimization approach can be identified and implemented in every individual Fertility unit maximizing their potential for effective Fertility treatment provision.

CHAPTER VI:

SUMMARY, IMPLICATIONS, AND RECOMMENDATIONS

6.1 Summary

ART (Assisted Reproductive Techniques) has revolutionized fertility treatment for infertile couples with rapid advancements in modern science. Infertility has been a taboo for ages, but advancements in technology have made it possible for millions of couples to find suitable treatment options.

The refinement of techniques in assisted reproductive technology opens up opportunities for finding solutions to fertility problems for a wider population. The journey began centuries ago and led to improvements in modern medicine, giving hope to those in need.

This thesis has looked at all important parameters driving cost implications for Fertility hospitals in India. Improving access to care of IVF is dependent on the ground level management personnel and clinical coordinators and decision makers in the industry.

The results of the survey and calculated savings indicate that actual calculated parameters rankings are widely different than the Survey respondents. A gap in understanding is identified in Fertility stakeholders considering the financial implications of various interventions on Fertility practice.

As a huge lacuna in understanding of cost parameters is identified and demonstrated in the survey, first off, a requirement of Auditing and management services regarding financial prudence and cost saving is required in the field. Following the discussion in this thesis a Cost optimization approach can be identified and implemented in every individual Fertility unit maximizing their potential for effective Fertility treatment provision.

6.2 Implications

Most large clinics doing above 1000 IVF cycles per annum were not included among the survey respondents. Most of this data comes from centers conducting 150-500 cycles a year. It was approximated in 2015 that about 80% of centers in India fall in this category.

This data should be revisited after evaluating statistics of various Chains of Fertility Centers like Indira IVF, Nova IVF, Birla IVF, ART Clinics etc., but it should be valid for most centers that fall into up to 500 cycles a month category or even beyond. Higher volumes in IVF do not necessarily affect per cycle costs per intervention but will most likely be skewed towards per cycle negotiation in terms of consumables and lower per operating costs.

6.3 Recommendations for Future Research

Future Research or Interventions can focus on a general template for Cost Optimization process change to be monitored or checked against the current practices.

The process as inferred from the current data collected in the survey suggests that a change management approach could benefit the Cost optimization methodology of research.

Eash sub process of the main process is segregated, and the current individual cost and manpower required for the sub process is identified. Once all the sub process are identified and cost & Manpower is accounted for each individual sub process is audited and discussed for cost optimization (cost or manpower).

All such cost optimization opportunities are identified and discussed, a small pilot project with recommended change in the sub is tested and on successful results the change is permanently implanted in the process.

The changes can be one at a time to multiple at a time depending upon the conclusion of the team and the process owners.

6.4 Conclusion

This seminal work on quantitative estimation of cost saving methodology and cost optimization approaches for Fertility practice in India with nationwide survey provides important information about the current state of Fertility practice in India. Most practitioners as per survey are highly inaccurate in assessing the impact of interventions on cost incurred by patient or the hospital. The reasons found are lack of understanding of the costing procedure or the feasibility and ease of use versus the actual cost savings that are done in the Fertility setting using the most popular interventions as collected by the survey.

The survey has used multiple methods to confirm that the choice of the respondants has been similar to their actual practices by asking multi modal questions i.e via using the ranking method and also the likert scale in five point to confirm and associate their responses with their actual preferences. This methodology and confirmatory tool was used to allow for the survey responses to be more robust and display actual real time conditions for decision making for the decision makers in the Fertility industry.

Compared to many other domains in healthcare which have reach maturation and have many legacy practices as well financial driven prudence and statistics as well as third party research information driven from the governmental, NGO as well the private research sector which have an advantage of centuries of work and research behind them, IVF is a fairly young branch of medicine practiced globally and has even a small timeframe in India considering formal Fertility units have been formed only two or three decades back. Normally Fertility Centers have been part of maternity units or extention

on gynaecological practices in India and have been driven primarily by individual gynaecologists and sometimes even other medical doctors like pathologists or clinical embryologists who were privy to the methodologies and most practices had fertility treatments like a trade secret.

With ongoing education, training as well as public discourse on fertility treatment, now it's a growing and mushrooming field with inclusion of various departments like embryology department, genetics department, finance department and patient outreach and management department. This growth and expansion of the Fertility treatment service itself and within India has led to an increased interest in the fiscal management of the internal processes of fertility treatment with the eventual goal of increased penetration as well increased profit margin for the organizations involved.

Even more pertinant is the fact that the patients as stakeholders continually and incrementally are demanding more economic and standardized services putting pressures of organizations for cost optimization.This work is future looking and presently urgent in nature due to these forces in play and the author is confident that this work will encourage even further deep dive of research and cost optimization practices in the fertility domain.

This detailed statistical thesis allows for a illusion correction and can be used to design training modules for fertility practitioners, administrators and IVF hospital owners. Apart from this, the use of this data from Indian scenario can be usd to create financial calculations and projections for the Fertility Units to plan and manage their patient and cost management approaches.

Further, any research focused on developing further financial or operations models can utilize the raw data as well as the expert panel statistical and algebric analysis to build upon financial and business research objectives in Fertility healthcare.

APPENDIX A:

SURVEY COVER LETTER AND INFORMED CONSENT

Dear Fertility Industry Expert,

We wish to invite you to participate in our academic survey on Cost Optimization Methods for Assisted Reproduction Centers in India'.

In this survey, IVF experts will be asked to complete a survey that asks questions about cost saving in their own centers. It will take approximately 15 minutes to complete the questionnaire.

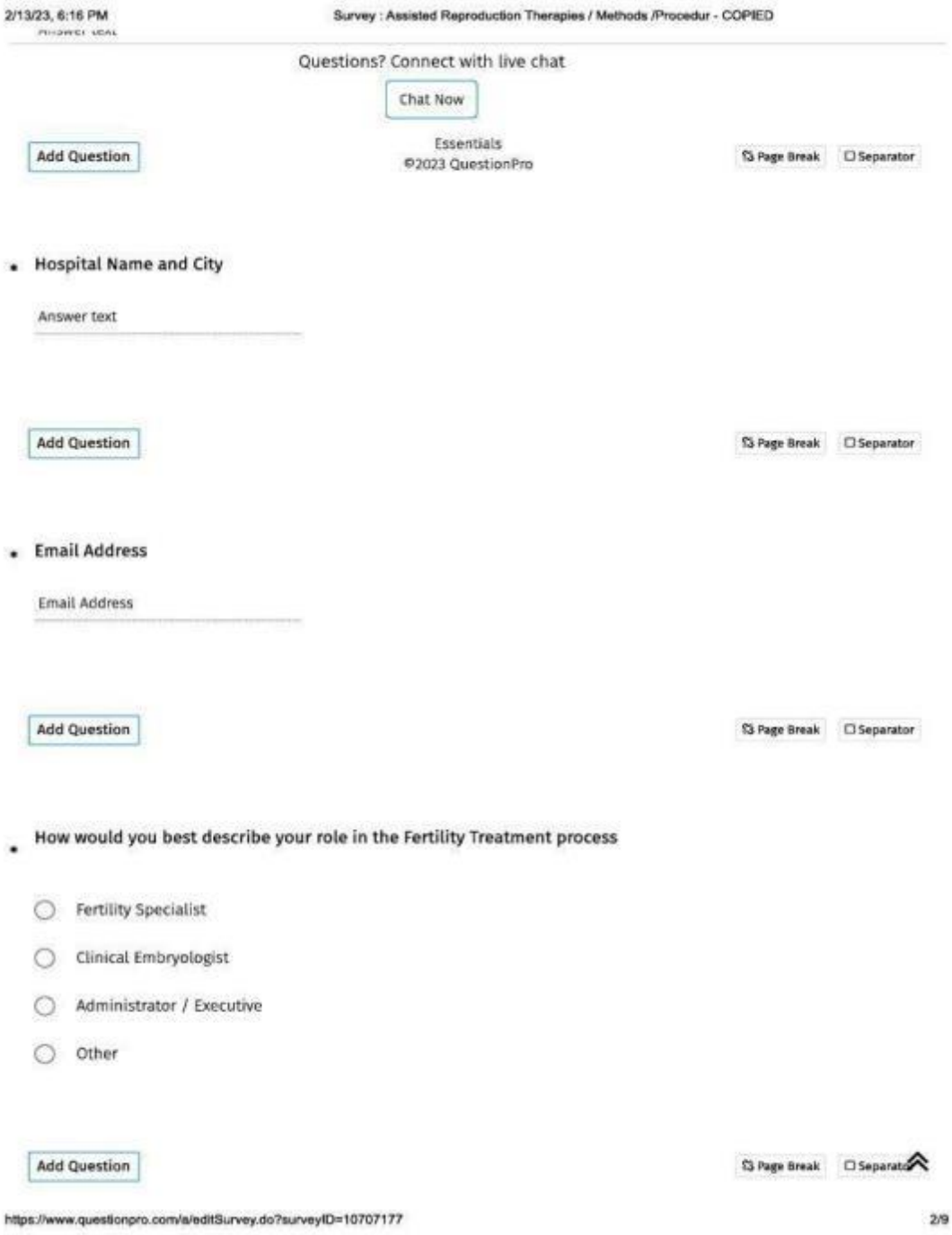
Your participation in this study is completely voluntary. There are no foreseeable risks associated with this project. However, if you feel uncomfortable answering any questions, you can withdraw from the survey at any point. It is very important for us to learn your opinions.

Your survey responses will be **strictly confidential and are collected anonymously** and data from this research will be reported only in the aggregate. Your information will be encrypted and will remain confidential. If you have questions at any time about the survey or the procedures, you may contact Mr. Pradeep Singh Kandari at 9820908587 or by email at cellsurebiotech@gmail.com

Thank you very much for your time and support. Please start with the survey now by clicking on the **Continue** button below;

APPENDIX B:

QUESTIONNAIRE



2/13/23, 6:16 PM Survey : Assisted Reproduction Therapies / Methods /Procedur - COPIED

Questions? Connect with live chat

Chat Now

Add Question

Essentials
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Page Break Separator

- Hospital Name and City

Answer text

Add Question

Page Break Separator

- Email Address

Email Address

Add Question

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- How would you best describe your role in the Fertility Treatment process

- Fertility Specialist
- Clinical Embryologist
- Administrator / Executive
- Other

Add Question

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https://www.questionpro.com/a/editSurvey.do?surveyID=10707177 2/9

- If you answered other in Question 1 , Please describe your role in Fertility Treatment process

Answer text

Add Question

Page Break Separator

- Do you Use the below interventions in practice

	Left Anchor	Right Anchor
	YES	NO
Diagnostic HSG/SSG	○	○
Clomiphene Citrate/ Letrozole for Ovulation Induction	○	○
Diagnostic Hysteroscopy/Laproscopy	○	○
Fertility Enhancing Laproscopic Surgeries	○	○
Intra Uterine Insemination (IUI)	○	○
Conventional Insemination (IVF)	○	○
Intra Cytoplasmic Sperm Injection (ICSI)	○	○
Pre Implantation Genetic Testing	○	○
Assisted Hatching	○	○

Add Question

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Add Question

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- How many cases per month does your Centre do of the below event/ procedure / patient

	0	100+
Diagnostic HSG/SSG	--	
Clomiphene Citrate/ Letrozole for Ovulation Induction	--	
Diagnostic Hysteroscopy/Laproscopy	--	
Fertility Enhancing Laproscopic Surgeries	--	
Intra Uterine Insemination (IUI)	--	
Conventional Insemination (IVF)	--	
Intra Cytoplasmic Sperm Injection (ICSI)	--	
Pre Implantation Genetic Testing	--	
Assisted Hatching	--	

Add Question

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- How much cost is associated per patient/procedure/event for below intervention for the Hospital/Centre

	0	20000+
Diagnostic HSG/SSG	--	

Clomiphene Citrate/ Letrozole for Ovulation Induction	--
Diagnostic Hysteroscopy/Laproscopy	--
Fertility Enhancing Laproscopic Surgeries	--
Intra Uterine Insemination (IUI)	--
Conventional Insemination (IVF)	--
Intra Cytoplasmic Sperm Injection (ICSI)	--
Pre Implantation Genetic Testing	--
Assisted Hatching	--

Add Question Page Break Separator

- **How much Cost Saving do you associate with each intervention below in your practice per patient**

	0	30000+
Keeping limited inventory(IVF drugs & lab consumables)	--	
Using minimal stimulation practices	--	
Elective freezing (no Freeze All)	--	
ICSI only for moderate and	--	

severe male infertility	
Reducing overhead expenses (management, accountancy, reception etc)	--
Batch IVF	--
Inhouse diagnostics	--
Day3 vs Day 5 embryo culture practices	--
Choosing Lower priced injectables (HMG vs recombinant , biosimilars vs original formulations)	--
Bulk lab culture media vs Small packs (30 ml culture media vs 10ml, Large Vitrification kits vs small kits)	--

Add Question

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- **Please rank the following in order of cost saving:**

Keeping limited inventory(IVF drugs & lab consumables)	1
Using minimal stimulation practices	2
Elective freezing (no Freeze All)	3
ICSI only for moderate and severe male infertility	4
Reducing overhead expenses (management, accountancy, reception etc)	5

Batch IVF	6
Inhouse diagnostics	7
Day3 vs Day 5 embryo culture practices	8
Choosing Lower priced injectables (HMG vs recombinant , biosimilars vs original formulations)	9
Bulk lab culture media vs Small packs (30 ml culture media vs 10ml, Large Vitrification kits vs small kits)	10

Top Anchor

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Add Question

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- **Please rate each intervention in terms of feasibility of use**

	Left Anchor				Right Anchor
	Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
Keeping limited inventory(IVF drugs & lab consumables)	○	○	○	○	○
Using minimal stimulation practices	○	○	○	○	○
Elective freezing (no Freeze All)	○	○	○	○	○
ICSI only for moderate and	○	○	○	○	○

severe male infertility					
Reducing overhead expenses (management, accountancy, reception etc)	○	○	○	○	○
Batch IVF	○	○	○	○	○
Inhouse diagnostics	○	○	○	○	○
Day3 vs Day 5 embryo culture practices	○	○	○	○	○
Choosing Lower priced injectables (HMG vs recombinant , biosimilars vs original formulations)	○	○	○	○	○
Bulk lab culture media vs Small packs (30 ml culture media vs 10ml, Large Vitrification kits vs small kits)	○	○	○	○	○

Add Question

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12 Questions

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