

SIG Newsletter

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KPI & Audit



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“KPIs decoded: The numbers that shape the IVF Outcomes”

In the fast-evolving landscape of assisted reproductive technology (ART), success is no longer defined solely by pregnancy rates. To ensure consistent quality, safety, and clinical excellence, IVF laboratories around the world have embraced **Key Performance Indicators (KPIs)** — objective, quantifiable metrics that help monitor and improve lab performance.

For embryologists and clinicians in India, where ART services are expanding and patient expectations are growing, a solid understanding of KPIs is essential. KPIs are not only tools for internal quality control but also vital for compliance, transparency, and accreditation.

What Are KPIs in IVF?

KPIs are standardized metrics used to track various stages of the IVF process — from ovarian stimulation and egg retrieval to embryo development and transfer. They serve as benchmarks for quality control, allowing labs to detect deviations, identify areas of improvement, and maintain reproducibility. These indicators are not just about outcomes, but also about **process efficiency, technical precision, and biological competence**.

When used correctly, KPIs help embryology teams:

- Maintain consistency across procedures
- Identify problems early
- Ensure adherence to protocols
- Benchmark against historical or international standards

Fig. 1 demonstrates an example of how Fertilization Rate – an important laboratory KPI is monitored over a period of time, helping not only in assessing laboratory performance over a period of time but also pre-empting any problems, if any, at an early stage.

The concept of KPIs gained recognition in IVF labs following the Vienna consensus. It primarily developed 19 performance indicators, including 12 KPIs, for laboratory outcomes such as fertilization rate, blastocyst formation rate, cryo-survival rate etc., in 'fresh' IVF and ICSI cycles. The consensus set competency values for minimum standard of care and benchmark

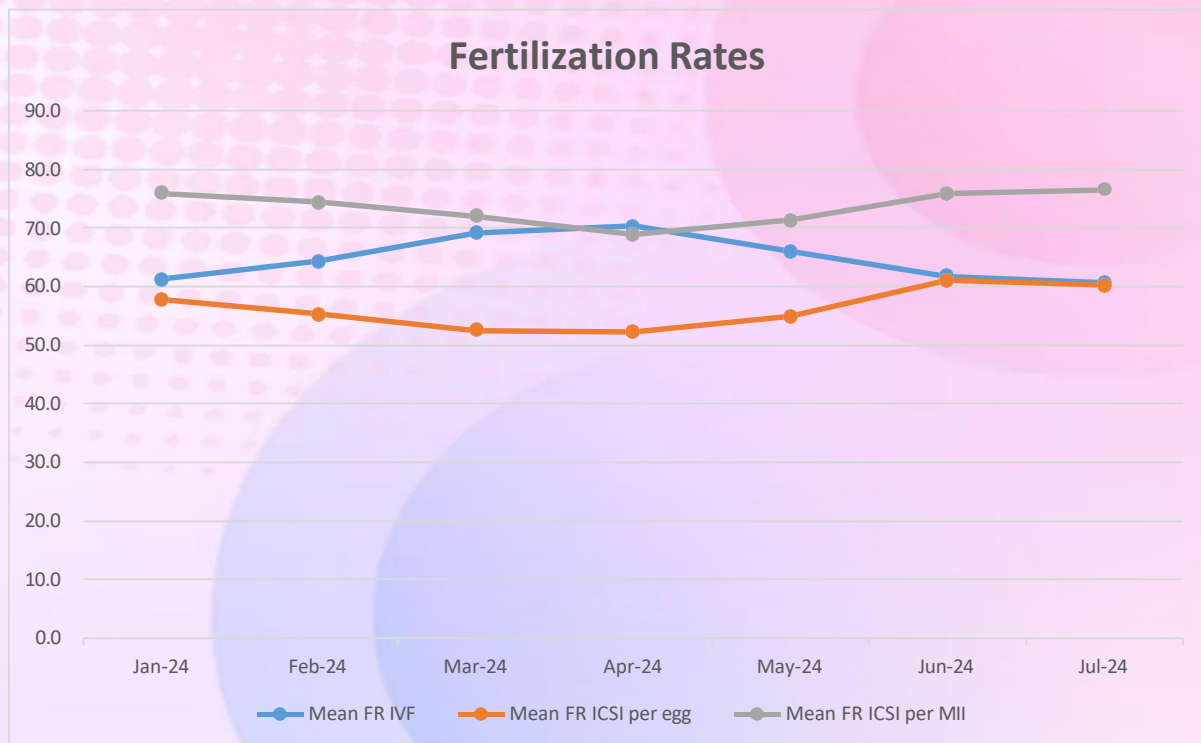


Fig.1 - Monitoring the Fertilization Rate over a period of time

values for aspirational standards. The only clinical aspect it represented was implantation rate. But considering the fact that the ultimate goal of ART is to provide a couple with a take home healthy baby, the true performance indicators needed to include clinical outcomes. This was aimed to be achieved in the Maribor consensus, where they proposed 6 performance indicators. These were cycle cancellation rate, rate of moderate/severe hyper-stimulation, proportion of mature (M-II) oocytes, complication after oocyte pick-up, clinical pregnancy rate and multiple pregnancy rate.

Live birth rate is the ultimate performance indicator for IVF labs. Though taking into consideration that it is influenced by multitude of factors, most of them outside of the laboratory's control and is difficult to follow-up on, no standard consensus has been reached on it as of yet.

National bodies such the Italian Society of Fertility and Sterility and Reproductive Medicine (SIFES-MR) alongside the Italian Society of Embryology, Reproduction and Research (SIERR), have come up with their own set of KPIs encompassing both laboratory and clinical outcomes

such as cycle cancellation rate, clinical pregnancy rate, miscarriage rate, fertilization rate, day 3 good quality embryo rate, blastocyst formation rate etc. (Vaiarelli et al., 2023).

Core KPIs in the IVF Lab: What to measure?

Several KPIs have been standardized by international bodies such as ESHRE and CAP, and they are increasingly being adopted in India. Some key laboratory KPIs include:

- **Fertilization Rate:** Percentage of oocytes retrieved that successfully fertilize (the 2PN stage).
- **Cleavage Rate:** Proportion of fertilized 2pn embryos that undergo normal cleavage within 48 to 72 hours. It is typically assessed on day 3 of embryo development.
- **Blastocyst Formation Rate:** Percentage of 2pn embryos reaching the blastocyst stage , reflecting culture conditions and embryo viability.
- **Blastocyst Utilization Rate:** Percentage of blastocysts transferred or frozen per 2pn embryos
- **Implantation Rate:** Number of gestational sacs observed per embryos transferred
- **Cryosurvival Rate:** Percentage of embryos that survive post-thawing, indicating cryopreservation efficacy.
- **Clinical Pregnancy Rate per Embryo Transfer:** A more outcome-oriented KPI, essential for assessing clinical effectiveness.
- **Live Birth Rate:** Percentage of total number of live births per total number of embryo transfers

Each of these indicators tells part of the story. When tracked consistently and interpreted together, they help create a comprehensive picture of lab performance.

Why KPI's Matter in IVF practice

In IVF, small changes in technique, environment, or protocol can significantly affect outcomes. KPIs act as an early warning system. For example, a sudden drop in fertilization rate may point

to issues with sperm preparation, insemination timing, or oocyte handling. Similarly, low blastocyst formation could reflect suboptimal culture media or incubator fluctuations.

By monitoring KPIs regularly, labs can:

- **Ensure Consistency:** Maintain high standards even with varying staff, protocols, or patient loads.
- **Enable Benchmarking:** Compare results within the clinic over time or with national/international standards (e.g., ESHRE guidelines).
- **Drive Continuous Improvement:** Identify trends, implement corrective actions, and optimize protocols.
- **Enhance Patient Trust:** Transparent reporting of KPIs builds confidence and sets realistic expectations.

Context Is Key: Interpreting IVF KPIs

While KPIs are essential tools for measuring performance in IVF laboratories, **their true value lies in how they are interpreted**. As highlighted by **Gardner et al. (2024)**, one of the most significant challenges in utilizing KPIs effectively is the **need to contextualize the data**, especially in light of the **heterogeneous nature of the reference patient population**.

Every IVF cycle is influenced by a wide range of patient-specific variables — including age, ovarian reserve, sperm quality, previous reproductive history, and underlying medical conditions. These factors significantly impact outcomes such as fertilization rates, blastocyst development, and implantation success. Without proper adjustment for these variables, KPI data can be misleading or even counterproductive.

For instance, comparing blastocyst formation rates across cycles without considering the patient's age or ovarian response may create false benchmarks. A clinic treating a high proportion of patients with diminished ovarian reserve may naturally have lower blastocyst rates compared to a clinic serving younger patients — not because of poor lab performance, but due to biological limitations.

Therefore it is vital that individual clinics should define a relevant reference population comprising of specific patient groups for KPI determination based on their clinical practice. ESHRE Special Interest Group of Embryology, 2011 and Alpha scientists in reproductive medicine, 2011 expert suggested that the **“reference population” should include patients that meet the following criterion:**

- **Female age less than 40 years of age,**
- **Own fresh oocytes undergoing IVF or ICSI,**
- **ejaculated sperm (fresh or frozen) and**
- **cycles without pre-implantation genetic testing.**

They have further revised this list to include cycles using vitrified/warmed oocytes taking the age at vitrification into account. Based on the analysis of all the included parameters, cycles can be predicted to be good to poor prognosis. Some labs go on to define “gold standard” in their reference population, including patients that are predicted to have very good prognosis. It includes patients who are undergoing their first IVF/ICSI cycle, young in age, having optimal number of oocyte and normal semen parameters.

Since the publication of the Vienna Consensus, there have been ongoing discussions about the need for updates and refinements to the KPI framework. The rapid advancements in ART techniques, such as blastocyst culture, freeze all cycles, preimplantation genetic testing and time-lapse imaging, have necessitated the inclusion of new indicators and the re-evaluation of existing ones. Additionally, the increasing focus on patient-centered care has led to calls for incorporating patient satisfaction and quality of life measures into the KPI framework. To this end, studies have been conducted to adjust the parameters of Vienna consensus to female age and further determine KPIs better suited for blastocyst culture and freeze all cycles (Zacà et al., 2022)(Wang et al., 2021). KPIs such as Day 3 and Day 5 good quality and usable embryo rate, blastocyst re-expansion rate, post thaw blastocyst hatching rate were evaluated. The Day 5 blastocyst development rate, which measures the percentage of embryos that reach the blastocyst stage on day 5 indicating optimal embryo development, has shown a strong correlation with pregnancy and live birth rates.

Therefore, **KPIs should not be interpreted in isolation**, but rather **within the clinical and demographic context** of the patient population being treated. Ideally, benchmarking should

involve stratification — grouping data based on age brackets, diagnosis categories, or stimulation protocols — to allow for fair and meaningful comparisons.

As Gardner et al. (2024) emphasize, “KPIs must be used with caution; without contextual filters, they risk becoming metrics without meaning.” For IVF labs aiming to improve quality while maintaining transparency, incorporating clinical context into KPI interpretation is not just good practice — it's essential for **responsible and accurate performance assessment**.

The Indian Perspective

India has witnessed exponential growth in IVF clinics over the last decade, with both metro cities and tier-2 towns now offering advanced ART services. While access has improved, this growth has also brought challenges related to quality, consistency, and regulation.

The introduction of the **ART and Surrogacy Regulation Acts** has shifted the focus towards standardization and accountability. These laws emphasize record-keeping, quality assurance, and periodic audits — all of which depend heavily on robust KPI monitoring.

However, in India's diverse demographic landscape, **contextualizing KPI benchmarks is especially important**. Fertility clinics may serve vastly different populations — from young PCOS patients in urban areas to older couples with low ovarian reserve in rural setups. Clinics must, therefore, **build their own internal baselines**, and use international benchmarks judiciously. The ART (Regulation) Act, 2021, and evolving ICMR guidelines emphasize quality monitoring and data-driven practice. Adopting KPIs not only aligns with global best practices but also supports accreditation, legal compliance, and international collaboration.

There is also a growing need for **national consensus on minimum and aspirational KPI thresholds**, adapted from bodies like ESHRE but tailored to the Indian context. Professional societies like the Indian Fertility Society (IFS) can play a pivotal role by facilitating KPI reporting, inter-lab comparisons, and continuous education.

Future Directions: Making KPIs Actionable

For KPIs to be truly impactful, they must be integrated into daily lab practice — not just stored in spreadsheets. Strategies to enhance the value of KPI tracking include:

- **Automated Data Capture:** Use of electronic witnessing and lab management systems for accurate, real-time KPI reporting.
- **Regular Audits:** Monthly or quarterly review of KPI trends by lab and clinical teams.
- **Case-Based Analysis:** When anomalies are detected, correlate KPIs with individual case histories.
- **Education and Training:** Continuous upskilling of staff based on KPI performance feedback.
- **Quality Improvement Plans:** Use KPIs to guide lab upgrades, changes in stimulation protocols, or procedural refinements.

Another evolutionary aspect of KPIs is the inclusion of Artificial Intelligence (AI) in its implementation (Sergeev, 2025). An important part of it is development of neural networks to efficiently process all the clinical and laboratory data and draw correlations to aid in the development of new and betterment of the existing KPIs.

Conclusion

KPIs in IVF labs are not just numbers — they are powerful tools that reflect precision, quality, and care. By embracing KPI-driven monitoring, Indian IVF clinics can move towards more reliable, transparent, and successful reproductive care. In a field where every detail counts, KPIs offer a scientific pathway to sustained excellence.

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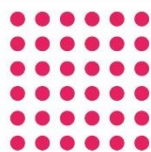
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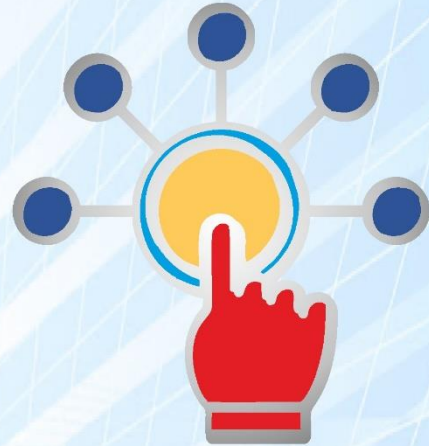
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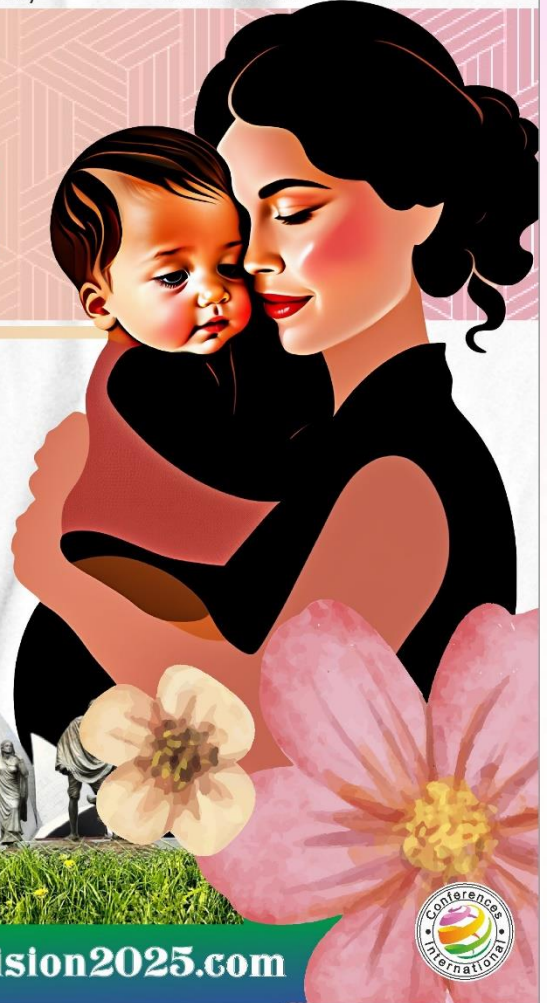
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