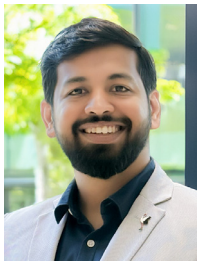
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ARTICLE

Systematic standardization improves compliance and performance across a large IVF network through audits and digitally enabled quality management



BIOGRAPHY

Naval Shah is Head of Embryology Operations and Quality Assurance at Indira IVF, India's largest IVF network. With a background in animal embryology, a Master's in Zoology, and an Advanced Diploma in Biotechnology, he brings over 17 years of experience, specializing in quality management, embryology training, and laboratory process optimization.

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KEY MESSAGE

Implementation of a structured, checklist-driven audit framework integrated with digital quality management was associated with improved compliance and laboratory performance. These findings support the role of scalable, standardized governance frameworks in harmonizing practices and strengthening quality assurance across multicentric corporate IVF networks.

ABSTRACT

Research question: Can systemic standardization via audits and digitally enabled quality management improve compliance and clinical outcomes across a large IVF network?

Design: An ambitious initiative was undertaken to develop a laboratory audit programme involving recruitment, selection and practical IVF laboratory training of personnel to constitute a specialist audit team, aiming to enhance quality, consistency and clinical outcomes across a large IVF network. In total, 149 audit checkpoints were included alongside cloud-based dashboards enabling multilevel live reporting against benchmarks, with scorecards facilitating training and process optimization, while monthly growth charts displaying changes in competency levels supported a continuous quality improvement loop. Effectiveness was assessed by a retrospective, multicentric, cross-sectional analysis of 34,461 treatment cycles involving intracytoplasmic sperm injection over 3 years across 30 centres. Degree of conformity was compared across 149 checkpoints in five categories

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KEY WORDS
Audit
Standardization
Corporate digitalization
Quality management
Continuous improvement

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(laboratory management, process, key performance indicators, laboratory equipment and documentation) post-audit compared with pre-audit.

Results: The primary outcome was compliance rate. Implementation of the audit framework improved the compliance rate significantly from a mean ± SD of 74.4% ± 7.6% pre-audit to 80.1% ± 7.8% post-audit ($P = 0.002$). Secondary outcomes included blastocyst rate, which increased significantly from a mean ± SD of 51.2% ± 7.6% pre-audit to 56.5% ± 8.2% post-audit ($P < 0.001$), and biochemical pregnancy rate, which increased significantly from a mean ± SD of 72.3% ± 6.5% pre-audit to 75.7% ± 4.8% post-audit ($P = 0.002$).

Conclusions: This investigation demonstrates that systematic audits and laboratory standardization may improve the compliance rate and embryological outcomes. These findings highlight the value of structured auditing, standardized practices, and continuous monitoring in enhancing IVF laboratory performance, and provide a practical framework for quality improvement across IVF clinics.

INTRODUCTION

IVF laboratories function within highly sensitive settings where oocyte and embryo development depends on intrinsic culture conditions and the extrinsic environment, which in turn affects the laboratory and clinical outcomes. The 2020 ALPHA Cairo consensus described how laboratory conditions, even with good-quality gametes, play a crucial role in IVF outcomes (*Cairo Consensus Group, 2020*). Air quality, temperature, pH stability, and control of volatile organic compounds or particulates are essential to preserve physiological balance (*Agarwal et al., 2017*; *Mortimer et al., 2018*; *Sciorio et al., 2021*; *Swain, 2010*). Media composition, protein supplements, and consumables (such as oils and plasticware) may introduce unrecognized toxicity, while procedural factors — including exposure to ambient conditions, incubator fluctuations, or excessive manipulation — can trigger oxidative stress and developmental arrest (*Martín-Romero et al., 2008*; *Simopoulou et al., 2018*). Human elements, from embryologist expertise to staffing patterns and adherence to standard operating procedures (SOP) and workload distribution, add further variability (*Basar, 2024*; *Shirasawa and Terada, 2025*). Embryo developmental potential and viability depend not only on underlying biology but also on clinical interventions, such as management of ovarian stimulation, along with functionality and consistency of laboratory practices.

Given the inherent complexity of IVF laboratory workflows, where multiple manual and automated steps intersect, reliance on individual expertise alone is insufficient to ensure consistent quality and safety. Consequently, structured quality frameworks have been proposed and adopted increasingly in IVF laboratories to move beyond operator-dependent practices. Total quality management provides a comprehensive approach by integrating inspection (audits), quality control and quality assurance into systems of continuous monitoring. When implemented in a coordinated manner, these components enhance traceability, minimize operational risk, and establish accountability, enabling early identification and correction of even minor deviations (*Mortimer and Mortimer, 2015*). Within this framework, auditing represents a central operational tool, providing a structured mechanism to assess compliance with SOP, detect deviations, and facilitate timely corrective and preventive actions. Accordingly, professional bodies, including the European Society of Human Reproduction and Embryology (ESHRE) (*Gianaroli et al., 2022*), *American Society of Reproductive Medicine (2021*, *2022*), Indian Society of Assisted Reproduction (*Malhotra et al., 2021*), and *College of American Pathologists (n.d.)*, have emphasized laboratory audits as a core component of quality management and regulatory compliance. However, despite the availability of these frameworks and recommendations, the extent to which systematic auditing influences IVF laboratory performance remains insufficiently explored.

The preponderance of existing reports has focused on single-centre experiences, demonstrating technical refinements such as culture conditions, workflow distribution, or introduction of key performance indicator (KPI) measurements and their importance for laboratory outcomes (*ESHRE Clinic PI Working Group et al., 2021*; *Vaiarelli et al., 2023*). These findings have depicted valuable insights into laboratory optimizations, but the importance of auditing as a governance strategy remains largely undefined. Notably, there is a lack of large-scale multicentric data evaluating the implications of systematic audits. In view of the paucity of this data, and as part of a continuous improvement programme, the authors' organization implemented a systematic audit across 30 of its IVF centres beginning in December 2020. The continuous improvement framework encompassed internal audits, unannounced checks, KPI-specific audits, laboratory benchmarking at individual embryologist level through to national level, digitalization of KPI, alarm and monitoring system refinements, and integration of an electronic witnessing system (EWS).

This study assessed the impact of implementation of systematic auditing of networked IVF laboratories by considering compliance, and embryological and clinical outcomes. It was postulated that enhanced adherence to SOP and compliance would result in higher blastocyst formation rates, improved blastocyst quality, and better early clinical outcomes. This study evaluated and compared pre- and post-audit laboratory performance involving more than 34,000 intracytoplasmic sperm injection (ICSI) cycles in 30 IVF centres over a period of 3 years.

MATERIALS AND METHODS

Study design

This was a retrospective, multicentric, cross-sectional analysis of 34,461 ICSI cycles between April 2019 and March 2022 across 30 centres of Indira IVF Hospital Limited (India). In December 2020, the organization implemented an audit department comprised of trained and experienced auditors, laboratory managers, and departmental heads. All laboratories were operated under centralized SOP and corporate infrastructure with uniform equipment, management systems, and working patterns, with heterogeneous treatment

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cycle volumes. The study protocol was approved by Indira IVF Hospital Institutional Ethics Committee (approval no. IIVF-UA00082, approval date 17 February 2025).

Settings and participants

All first-cycle patients underwent ICSI during the study timeframe and were included in the analyses. Patients who underwent their second or subsequent treatment cycle were excluded. The dataset was stratified into two cohorts: pre-audit implementation, comprising of 17,280 patients between April 2019 and March 2020; and post-audit implementation, involving 17,181 patients between April 2021 and March 2022. In total, 16,001 patients were excluded as the audit was incomplete during the coronavirus disease 2019 pandemic period from April 2020 to March 2021 due to travel restrictions. This investigation utilized the data from 30 centres that had completed exactly two full rounds of audit to enable comparison. For statistical analysis, the data were extracted from in-house standardized electronic medical records (EMR) developed by the Indira IVF IT team. The variables extracted from EMR were female age at embryo transfer, male age at embryo transfer, body mass index, endometrial thickness at embryo transfer, and baseline serum anti-Müllerian hormone.

The audit programme was implemented concurrently across all the participating centres. The audit was conducted jointly by a qualified, experienced auditor along with an embryology laboratory manager (designated senior embryologists). Prior to implementation, all auditors underwent 4 weeks of comprehensive, structured laboratory training at the reference laboratory (Indira IVF Hospital training laboratory). Each auditor received theoretical and hands-on experience in laboratory processes, including equipment handling, embryo culture, documentation, and technical IVF procedures of the embryology laboratory (oocyte retrieval, oocyte denudation, embryo and oocyte vitrification and warming, and ICSI). The training also encompassed familiarization with corporate SOP, equipment calibration and maintenance, along with audit protocols. Selected senior embryologists had a minimum of 5 years of experience and were trained in audit-specific procedures. Following completion of the training programme, auditors were deployed to their respective centres. To minimize interobserver variability and ensure standardization, all audit reports generated after the audit underwent centralized online validation by the Head of Embryology Quality Assurance/Quality Control prior to their release to individual centres. Additionally, cross-verification was implemented in subsequent phases, wherein auditors were assigned to centres other than those they audited routinely, further strengthening consistency and reproducibility across sites.

Audit framework procedures

Development of the audit tool

While implementing the audit programme, auditors jointly developed a standardized audit checklist and SOP. The audit checklist was implemented into the organization according to various guidelines and consensuses, which are documented in TABLE 1.

Auditors collaboratively finalized a checklist of 149 checkpoints within five categories: laboratory management, process, KPI, laboratory equipment, and documentation. This is presented in Supplementary Table 1 and FIGURE 1.

Whilst the audit was based on the predefined checklist, the auditors were also instructed to note additional observations as they arose. A mock validation of the audit was conducted at the reference laboratory prior to implementing it across all the participating sites.

Types of audit

The audit programme was implemented via five distinct audit categories:

- Planned audits – scheduled in advance with formal communication to the centre.
- KPI-based audits – performed when monitored performance fell below the predefined competency rate of the institution. KPI measurements were centralized and assessed independently.
- Unannounced audits – performed without prior notice triggered via concerns such as reported SOP

TABLE 1 INTERNATIONAL GUIDELINES AND STANDARDS USED FOR DEVELOPMENT OF THE IVF LABORATORY AUDIT CHECKLIST

Source guideline/standard	Year	Type of document
Indian Council of Medical Research guidelines (*Indian Ministry of Health and Family Welfare et al., 2005*)	2005	National regulatory guideline
American Society for Reproductive Medicine recommendations (*American Society for Reproductive Medicine, 2008*)	2008	Professional society committee opinions
International Federation of Fertility Societies (*Ory et al., 2014*)	2014	Global ART practice guideline
Quality and risk management in the IVF laboratory (*Mortimer and Mortimer, 2015*)	2015	Textbook
European Society of Human Reproduction and Embryology guidelines for good practices in IVF laboratories (*De Los Santos et al., 2016*)	2016	International ART laboratory guideline
ISO 9001 Quality Management System (*Bento and Esteves, 2016*)	2016	International quality standard
Vienna consensus (*ESHRE Special Interest Group of Embryology, Alpha Scientists in Reproductive Medicine, 2017*)	2017	International consensus statement
Quality and Accreditation Institute standards (*Quality and Accreditation Institute, 2018*)	2018	Accreditation standard
Cairo consensus (*Cairo Consensus Group, 2020*; *Mortimer et al., 2018*)	2018 2020	International consensus statement
Internal technical standard operating procedures, second edition	2020	Institutional documents
Equipment quality manuals and material safety data sheets	—	Manufacturer guidelines

ART, assisted reproductive technology.

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IVF LABORATORY AUDITS	Category	Sub-Category
	Laboratory Management	Facility and Laboratory Management
		Personnel
		Equipment Management
		Documentation Management
		Material Management
		Safety
		Biomedical Waste Management
	Process	Andrology
		Oocyte Retrieval
		Insemination and ICSI
		Embryo Culture, Grading and Transfer
		Cryopreservation
	KPI	Oocyte Maturation Rate
		Blastocyst Rate
		Good-quality Blastocyst Rate
		Equipment Breakdown Turnaround Time
	Laboratory Equipment	All laboratory equipment
	Documentation	Hard Copies
		Soft Copies

FIGURE 1 Domain-based structure of the IVF laboratory audit checklist. The checklist comprises five categories, namely, laboratory management, process, key performance indicators (KPI), laboratory equipment, and documentation. There are various subcategories within each of these categories. ICSI, intracytoplasmic sperm injection.

deviations, reported complaints, or internal quality alerts.
- Re-audits – executed to validate the sustained implementation of the corrective actions.
- Virtual audits – performed via virtual conferencing following up for unresolved conformities.

Audit process flow

Each audit implementation followed a standard five-step process:

- Audit plan and schedule – for planned audits, a formal communication via e-mail was sent to the centre head and embryologist in charge, detailing the audit date, time, auditors and agenda.
- Opening onsite meeting – auditors performed an initial briefing with the included team from the centre, and outlined the objectives, agenda and expectations of the ongoing audit.
- Audit execution – auditors performed systematic evaluations based on the predefined checklists across all the domains, and designated senior embryologists oversaw process adherence from oocyte retrieval to embryo transfer in accordance with the SOP.
- Audit reporting – a detailed audit report summarizing the observations and non-conformities was generated and sent to the embryology laboratory manager and centre head via e-mail after completion of the audit. Audit observations were categorized into three levels of compliance:
  - Complete compliance: all applicable standards, regulations, policies and procedures were adhered to fully, with no deviations identified. Sufficient and appropriate documented evidence was available to demonstrate effective implementation and sustained compliance.
  - Partial compliance: most requirements were met; however, one or more elements were only partially fulfilled, or minor gaps were identified. While these gaps did not compromise overall compliance, corrective actions were required.
  - Non-compliance: requirements were not met, or major deviations were identified with the potential to adversely impact laboratory processes, patient safety, quality outcomes, or regulatory compliance.

During the audit, each checkpoint was assigned a compliance score of 10, 5 or 0, representing complete compliance, partial compliance or non-compliance, respectively. For the laboratory equipment component of the audit, in which each piece of equipment was assessed based on multiple parameters, if a parameter for a given piece of equipment was determined to exhibit partial compliance or non-compliance, that piece of equipment was assigned an overall compliance status of partial compliance or non-compliance, respectively, and a compliance score of 5 or 0, respectively. Centres were recommended to submit the response on the observations, closure or action plan for audit closure within 7 working days.

- Follow-up: the integration of corrective action plans was verified through evidence or re-audit. Once the auditors were satisfied with the corrective actions, the audit was formally closed.

Standardization and quality oversight

The conceptualization and planning of the audit implementation and programme were executed under the supervision of respective functional departmental heads as demonstrated in FIGURE 2. Additionally, the audits comprising performance check, benchmarking, KPI monitoring, and scorecard assessment were also overseen by the Head of Embryology Quality Assurance/Quality Control. Notably, upon completion of each audit, the centre-specific reports, including identified non-conformities, and closure documentation, were submitted to the Head of Embryology Quality Assurance/Quality Control for review.

Digital KPI monitoring and scorecard assessment

A comprehensive digital KPI monitoring system was established concurrently with implementation of the audit programme. Data collection was standardized using the same tools, platform, and data validation practice across all clinics (using electronic records that were developed and standardized by the in-house IT team and verified manually), and was synchronized to cloud-based software – PowerBI (Microsoft, USA) (dashboards developed by the in-house IT team in association with the Head of Embryology Quality Assurance/Quality Control) that aggregated the information and evaluated the KPI through visual interfaces (FIGURE 3A). The dashboards generated had multilevel assessment, from embryologist level to centre level and national level. Each embryologist's outcomes were compared against the centre and national benchmarks through individualized scorecards (FIGURE 3B). Additionally, a scorecard was prepared for every embryologist populated from four existing KPI as demonstrated in FIGURE 3C. The four

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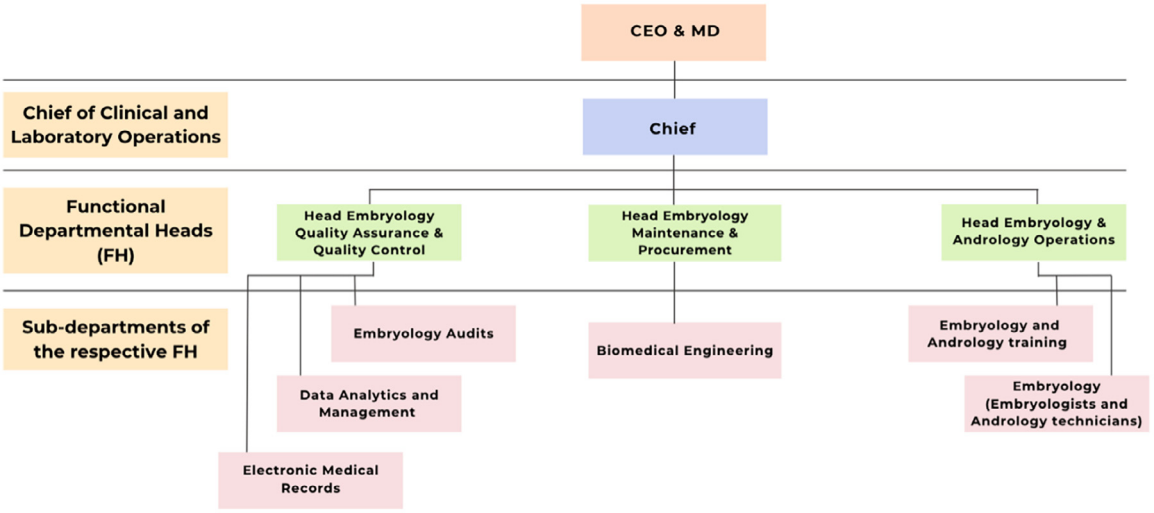


FIGURE 2 Organizational governance structure. Organizational chart showing the hierarchy under which the conceptualization and planning of the audit implementation and programme were executed. CEO, Chief Executive Officer; MD, Managing Director.

KPI evaluated were overall laboratory success rate (KPI 1), embryologist-specific autologous frozen embryo transfer (FET) success rate (KPI 2), embryologist-specific autologous blastocyst rate (KPI 3), and embryologist-specific autologous good-quality blastocyst rate (KPI 4). Donor cycles were excluded from the calculation of KPI 2, KPI 3 and KPI 4 due to the risk of bias based on the variable proportion of these cycles across the centres. Blastocyst and good-quality blastocyst rates were included as KPI, as all cycles during the study period involved blastocyst culture and transfer. Each KPI contributed a predefined weight to the balanced scorecard, with KPI 1 contributing 15%, KPI 2 contributing 30%, KPI 3 contributing 35%, and KPI 4 contributing 20%, resulting in a maximum total score of 100%. The included KPI were defined as follows:

- Overall laboratory success rate (KPI 1): the percentage of autologous and donor transfer procedures resulting in a positive biochemical pregnancy [β-human chorionic gonadotrophin (β-HCG) concentration >25 IU/l detected via maternal blood testing], calculated as the number of positive biochemical pregnancies achieved divided by the total number of autologous and donor transfer cycles during the reporting period multiplied by 100.
- Embryologist-specific autologous FET success rate (KPI 2): the percentage of autologous FET procedures resulting in a positive biochemical pregnancy (β-HCG concentration >25 IU/l detected via maternal blood testing), calculated as the number of positive biochemical pregnancies achieved following autologous FET divided by the total number of autologous FET cycles performed multiplied by 100.
- Embryologist-specific autologous blastocyst rate (KPI 3): the percentage of autologous metaphase II (MII) oocytes inseminated that developed into blastocysts (day 5 or day 6), calculated as the total number of autologous blastocysts formed divided by the total number of autologous MII oocytes inseminated multiplied by 100.
- Embryologist-specific autologous good-quality blastocyst rate (KPI 4): the percentage of good-quality blastocysts (defined as those graded as >3BB according to the Gardner and Schoolcraft grading system), calculated as the number of autologous good-quality blastocysts divided by the total number of autologous MII oocytes inseminated via ICSI multiplied by 100.

Simultaneously, every embryologist KPI was compared against benchmarks, and a final balanced scorecard was generated as shown in FIGURE 3D. With the aim of minimizing subjectivity associated with blastocyst assessment, extensive training, competency assessment and refresher training were practiced routinely within the network to harmonize grading practices across all embryologists. Additionally, embryologists at low-performance centres for blastocyst grading were selected for revaluation and reassessment, supported by refresher training, independent peer review, and expert oversight until acceptable performance was demonstrated. Moreover, the scorecard framework facilitated targeted training for individual embryologists and process optimization for respective centres by highlighting performance gaps and staff-specific trends. Alongside, monthly growth charts displayed progressive changes in competency levels, thereby supporting a continuous quality improvement loop.

Implementation and digitalization of electronic witnessing system

Preceding audit implementation, the study institution integrated an EWS (RI Witness; CooperSurgical, Denmark). This radiofrequency identification (RFID) technology was employed, with all consumables tagged to facilitate automated documentation and verification of every handling event and procedure. All procedural workflow of the laboratory was timestamped and transmitted to a secure, cloud-based dashboard accessible to senior management. The systematic evaluation of these timestamps allowed auditors to assess the duration of each embryological procedure (e.g. oocyte retrieval, denudation and ICSI) and identify the potential deviations from SOP. For example, during oocyte retrieval, insertion of the RI Witness card by the patient in the operating theatre, followed by detection and pairing of the RFID-tagged oocyte collection dish at the workstation, was recorded as the start timestamp. The end timestamp was recorded when the oocyte collection dish and the oocyte incubation

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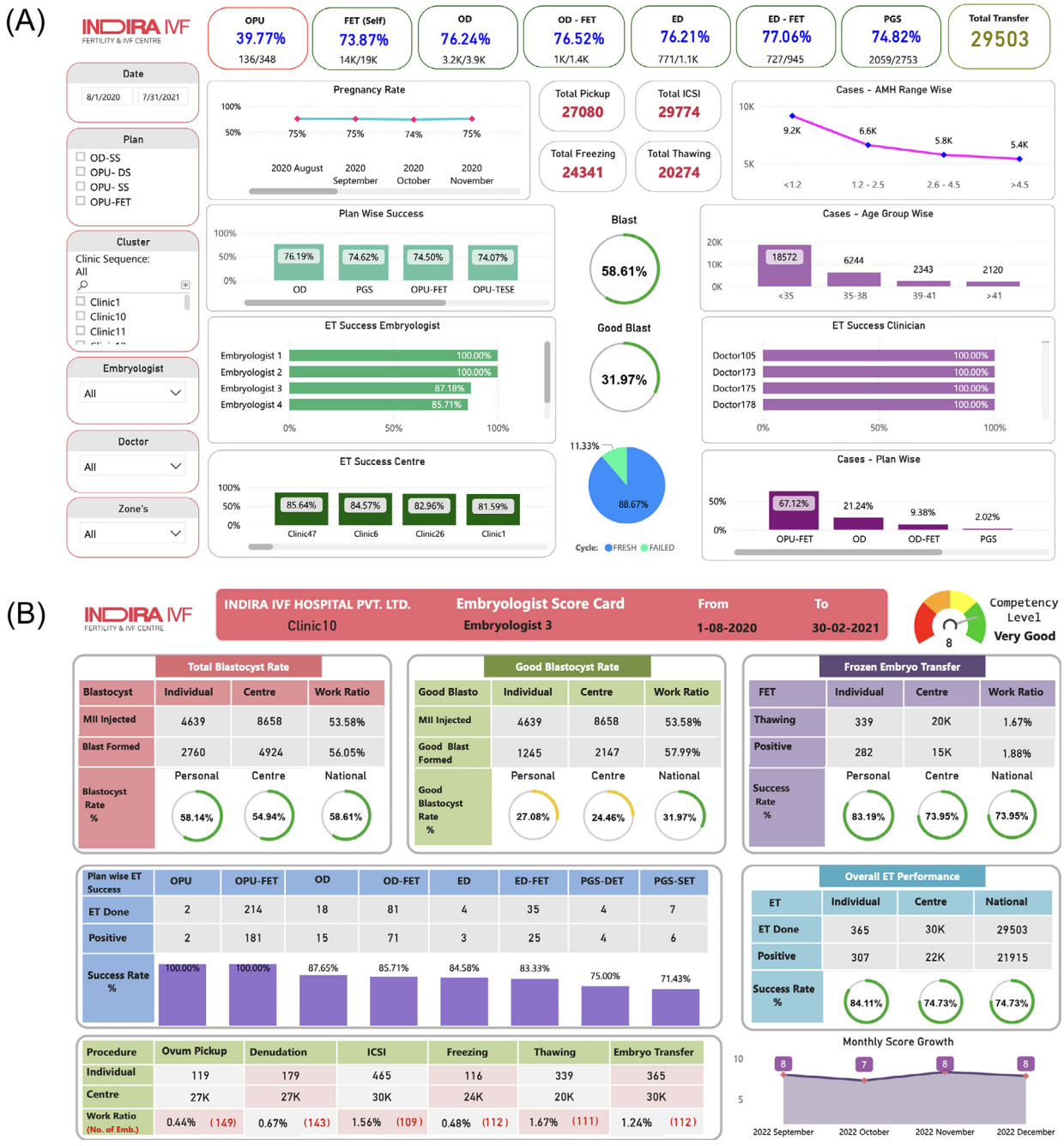
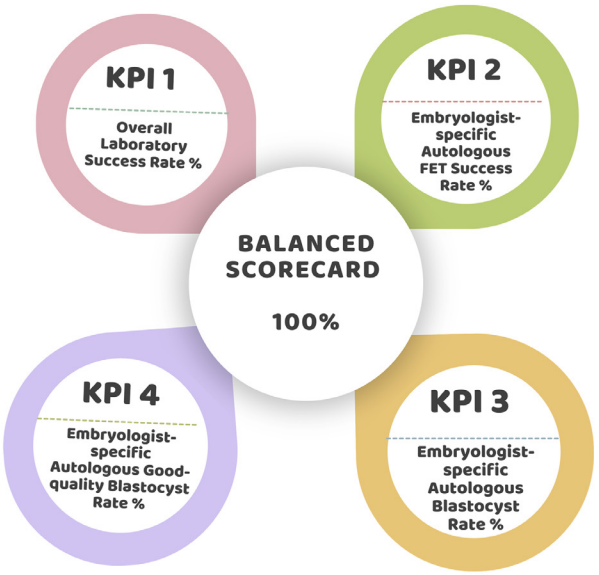


FIGURE 3 Dashboards and scorecard assessment. (A) Screenshot of the key performance indicator (KPI) monitoring dashboard showing representative data. (B) Screenshot of the embryologist scorecard showing representative data. (C) Embryologist balanced scorecard based on four KPI: overall laboratory success rate (%), embryologist-specific autologous frozen embryo transfer (FET) success rate (%), embryologist-specific autologous blastocyst rate (%), and embryologist-specific autologous good-quality blastocyst rate (%), representing KPI 1, KPI 2, KPI 3 and KPI 4, respectively. Each KPI contributed a predefined weight to the balanced scorecard, with KPI 1 contributing 15%, KPI 2 contributing 30%, KPI 3 contributing 35%, and KPI 4 contributing 20%, resulting in a maximum total score of 100%. The balanced scorecard was developed for each embryologist to facilitate monitoring and evaluation of individual KPI performance. (D) Screenshot of the embryologist scorecard comparing the performance of individual embryologists with representative data shown. Scores were assigned based on the criteria depicted in FIGURE 4. Performance was categorized using a four-colour grading system: red, orange, yellow and green, representing poor, average, good and excellent performance, respectively. Embryologists from all clinics were evaluated collectively on one dashboard, enabling comparison of individual performance across the entire network. OPU, oocyte pick-up; OD, oocyte donation; ED, embryo donation; PGS, preimplantation genetic screening; ICSI, intracytoplasmic sperm injection; AMH, anti-Müllerian hormone; ET, embryo transfer; Blast, blastocyst; Good Blast, good-quality blastocyst; DET, double embryo transfer; SET, single embryo transfer.

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(C)



(D)

INDIRA IVF
FERTILITY & IVF CENTRE

Embryologist Score
INDIRA IVF HOSPITAL PVT. LTD.

Date: 7/1/2021 – 7/31/2021
Employee Name: All

Clinic Name	Embryologist Name	Overall Blast Score	Overall Good Blast Score	Overall FET Score	Overall Lab Score	Final Score
Clinic 12	Embryologist 92	10	10	9	10	10
Clinic 5	Embryologist 157	10	10	9	8	9
Clinic 11	Embryologist 7	9	9	9	10	9
Clinic 27	Embryologist 38	10	8	9	10	9
Clinic 6	Embryologist 68	10	9	8	10	9
Clinic 8	Embryologist 146	10	9	10	8	9
Clinic 33	Embryologist 103	10	9	9	8	9
Clinic 1	Embryologist 36	10	5	10	10	9
Clinic 26	Embryologist 78	8	8	10	10	9
Clinic 10	Embryologist 85	9	9	8	10	9
Clinic 14	Embryologist 62	8	8	9	10	9
Clinic 34	Embryologist 76	10	9	8	6	9
Clinic 21	Embryologist 57	8	9	9	8	8
Clinic 24	Embryologist 124	10	8	8	8	8
Clinic 15	Embryologist 13	6	8	10	10	8
Clinic 32	Embryologist 171	10	1	10	10	8
Clinic 3	Embryologist 20	10	5	9	8	8
Clinic 33	Embryologist 37	10	9	5	8	8
Clinic 33	Embryologist 34	10	8	5	8	8
Clinic 43	Embryologist 133	9	10	5	8	8
Clinic 17	Embryologist 19	10	10	5	6	8
Clinic 6	Embryologist 48	9	1	9	10	8

FIGURE 3 Continued.

dish were co-identified, indicating completion of oocyte processing and start of oocyte incubation. The interval between these events represented the total duration of the oocyte retrieval procedure.

Alarm and monitoring system

In tandem with the audit framework, an automated alarm system was co-developed tailored to institutional protocols and laboratory equipment, and deployed across all the centres of the organization. The LabCare system (Shivani Scientific, India) implemented a network of digital sensors for monitoring of critical parameters — including temperature, humidity, CO_2 and O_2 concentrations, gaseous flow, and water and liquid nitrogen levels — according to what was applicable to the required equipment. The system was designed to track incubators, refrigerators and cryotanks, translating real-time monitored data to cloud-based dashboards accessible to both the local laboratory team and the senior management team. In case of any deviation beyond predefined thresholds determined by the internal QMS team for all the different quality characteristics (e.g. temperature and gas concentrations) of the different pieces of equipment, the system automatically initiates alerts via SMS, e-mail and telephone calls. This automated system follows a five-tier hierarchical escalation matrix, with notifications escalated sequentially (from the junior embryologist to the senior embryologist, then to the laboratory manager, then to the floor manager and finally to the centre clinical director) if the deviation remains unresolved. This automated escalation framework enabled

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secured 24/7 equipment oversight and equipment fluctuations.

Construction of laboratory benchmark

To support the audit programme, the study institution established internal laboratory performance benchmarks constructed from a comprehensive 6-month dataset (September 2019 to February 2020) from across the whole network. This dataset included 16,827 overall transfers (fresh and vitrified-warmed embryo transfers) with 8848 FET from autologous and donor patient ICSI cycles, consisting of 78,195 blastocysts [40,452 from autologous oocyte ICSI cycles and 37,743 from donor oocyte ICSI cycles, of which 24,547 (61%) and 22,418 (59%) were good-quality blastocysts [grade >3BB according to the Gardner and Schoolcraft criteria (*Gardner and Schoolcraft, 1999*), respectively]. Based on these data, organization-wide competency thresholds and performance benchmarks were established for key laboratory and clinical indicators, namely, blastocyst rate, good-quality blastocyst rate, FET rate, and overall laboratory success rate:

- Blastocyst rate: the total number of blastocysts formed in both autologous and donor cycles divided by the total number of MII oocytes inseminated via ICSI multiplied by 100.
- Good-quality blastocyst rate: the total number of good-quality blastocysts formed by both autologous and donor cycles (defined as grade >3BB according to the Gardner and Schoolcraft grading system) divided by the total number of MII oocytes inseminated via ICSI multiplied by 100.
- FET rate: the percentage of autologous and donor FET procedures resulting in a positive biochemical pregnancy (β-HCG concentration >25 IU/l detected via maternal blood testing) calculated as the number of positive biochemical pregnancies achieved following autologous and donor FET divided by the total number of autologous and donor FET cycles performed multiplied by 100.

Benchmark derivation employed statistical process control methods, including control charts and Shewhart charts, and was aligned with internationally recognized performance standards outlined in the Vienna consensus (*ESHRE Special Interest Group of Embryology and Alpha Scientists in Reproductive Medicine, 2017*). These internally derived benchmarks served as reference standards for evaluating centre-level performance during audit implementation, and for identifying deviations requiring corrective action (FIGURE 4).

Outcome measures

The primary outcome of this study was the compliance rate (%) calculated via adherence to the 149 checkpoints, representing overall adherence to audit parameters. The compliance rate (%) was calculated as: (sum of the scores for complete compliance, partial compliance and non-compliance ÷ 1490) × 100, where 1490 represents the maximum possible score (149 checklist items × 10 points, assuming complete compliance for all items). Additionally, pre-audit compliance was defined as compliance recorded in the first audit, and post-audit compliance was defined as compliance achieved in the second (final) audit.

Secondary outcomes included key embryological and clinical performance indicators. The blastocyst rate was calculated based on the number of blastocysts developed divided by the total number of MII oocytes inseminated via ICSI multiplied by 100. The good-quality blastocyst rate was defined as the total number of morphologically good-quality blastocysts formed divided by the total number of MII oocytes inseminated via ICSI multiplied by 100. Blastocyst grading was conducted according to the Gardner and Schoolcraft grading system, and embryos with grade >3BB were categorized as good-quality blastocysts (*Gardner and Schoolcraft, 1999*). The biochemical pregnancy rate was defined as the percentage of embryo transfers resulting in positive serum β-HCG (>25 IU/l) tested via maternal blood tests.

Statistical analysis

Statistical analysis was performed using SPSS Statistics version 28.0 (IBM, USA). Clinical outcomes were expressed as percentages for every centre in each cohort. The point estimate and 95% CI were derived using the Wilson method. The mean ± SD for the 30 centres were calculated and compared between the pre-audit and post-audit phases. Statistical analyses of the various rates at individual centres were performed by calculating the 95% CI. Additionally, patients' characteristics were compared between pre- and post-audit using the Mann–Whitney *U*-test, where $P < 0.05$ was considered significant. For analysis of cumulative compliance, blastocyst, good-quality blastocyst and biochemical pregnancy rates, the paired *t*-test was used, where $P < 0.05$ was considered significant. The data were visualized using density plots in both the pre-audit and post-audit cohorts. The visualized data were plotted via RStudio (*R Core Team, 2024*) using the ggplot2 package (*Wickham, 2016*).

RESULTS

Study population

Across all cycles, 500,019 MII oocytes were retrieved (247,259 pre-audit, 252,760 post-audit). In total, 256,769 blastocysts were formed (118,094 pre-audit, 138,675 post-audit), of which 147,030 were classified as good quality (73,287 pre-audit, 73,743 post-audit) as demonstrated in TABLE 2. The characteristics of the patients who underwent embryo transfers were comparable pre-audit and post-audit (Supplementary Table 2).

Primary outcome: compliance rate

Implementation of the audit framework was associated with a marked improvement in overall compliance with embryology laboratory protocols (TABLE 3 and FIGURE 5A). The mean ± SD compliance rate increased from 74.4% ± 7.6% (95% CI 71.5–77.1%) pre-audit to 80.1% ± 7.8% (95% CI 77.2–83.0%) post-audit ($P = 0.002$), representing a mean absolute increase of 5.7%. Centre-level analysis showed that 24 of 30 centres showed an increased compliance rate post-audit, two centres maintained the same compliance rate post-audit, and four centres showed a decreased compliance rate post-audit. The greatest improvement was observed at Centre H (increase of 27% from 49% to 76%), whereas the largest decline occurred at Centre J (decrease of 17% from 81% to 64%). Centre-level data are provided in Supplementary Table 3, with a distribution plot in Supplementary Figure 1.

Secondary outcomes

Blastocyst rate

The mean ± SD blastocyst rate increased from 51.2% ± 7.6% (95% CI 48.3–54.0%) pre-audit to 56.5% ± 8.2% (95% CI 53.3–59.5%) post-audit ($P < 0.001$) – an absolute increase of 5.2% (TABLE 3 and FIGURE 5B). Centre-level trends (Supplementary Table 4) revealed that 23 of 30 centres improved their blastocyst rate post-audit, with the largest increase at

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KPI		RATE RANGE	SCORE	PERFORMANCE CATEGORY
Blastocyst rate		Below 31%	1	Poor
		31-34%	3	Weak
40%	49%	35-39%	5	Below Average
		40-46%	6	Average
		47-51%	8	Very good
Competency Threshold	Benchmark	52-58%	9	Excellent
		Above 58%	10	Outstanding
Good-quality blastocyst rate		Below 16%	1	Poor
		16-18%	3	Weak
23%	30%	19-22%	5	Below Average
		23-27%	6	Average
		28-32%	8	Very good
Competency Threshold	Benchmark	33-37%	9	Excellent
		Above 37%	10	Outstanding
FET rate		Below 54%	1	Poor
		54-60%	3	Weak
66%	72%	61-65%	5	Below Average
		66-69%	6	Good
		70-74%	8	Very good
Competency Threshold	Benchmark	75-84%	9	Excellent
		Above 84%	10	Outstanding
Overall laboratory success rate		Below 58%	1	Poor
		58-61%	3	Weak
66%	74%	62-65%	5	Below Average
		66-71%	6	Good
		72-76%	8	Very good
Competency Threshold	Benchmark	76-82%	9	Excellent
		Above 82%	10	Outstanding

FIGURE 4 Laboratory benchmarks and competence thresholds. Schematic showing the benchmarks and competency thresholds for the blastocyst, good-quality blastocyst, frozen embryo transfer (FET) and overall laboratory success rates. Rates within a specific range were converted to a score. The rate ranges corresponding to each score and the corresponding definitions and performance categories are shown. Scores were assigned according to the distance of the observed key performance indicator (KPI) value from the benchmark, relative to the SD of that KPI. Lower scores represented values progressively further below the benchmark, while higher scores represented values at, close to, or above the benchmark. Where an SD could not be subdivided into equal intervals without introducing fractional percentage cut-offs, the SD interval was divided into practical whole-percentage rate ranges. The blastocyst rate was defined as the percentage of blastocysts among the total number of metaphase II oocytes inseminated. The good-quality blastocyst rate was defined as the percentage of good-quality blastocysts (defined as grade >3BB according to the Gardner and Schoolcraft criteria) among the total number of metaphase II oocytes inseminated. The FET rate was calculated as number of biochemical pregnancies (defined as a β-human chorionic gonadotrophin concentration >25 IU/l detected via maternal blood testing) following FET divided by the total number of FET procedures performed multiplied by 100. The overall laboratory success rate was calculated as number of biochemical pregnancies following fresh embryo transfers and FET divided by the total number of fresh embryo transfers and FET performed multiplied by 100. The colours denote the performance category (red denotes poor and weak; orange denotes below average; yellow denotes average and good; green denotes very good, excellent and outstanding).

Centre M (increase of 18.1%, from 42.0% to 60.1%). Five centres experienced a decline post-audit, most notably Centre N (decrease of 7.7% from 62.6% to 54.9%). The distribution of centre-level blastocyst rates pre- and post-audit is visualized in Supplementary Figure 2.

Good-quality blastocyst rate

The mean ± SD good-quality blastocyst rate showed a modest, non-significant increase from 31.3% ± 5.0 pre-audit to 31.7% ± 6.1 post-audit (TABLE 3 and FIGURE 5C). At the centre level (Supplementary Table 5), 17 centres demonstrated an increase, with the largest improvement in Centre G (increase of 10.8% from 30.8% to 41.6%). Additionally, 13 centres experienced a decrease, with the most pronounced decline at Centre AB (decrease of 9.3% from 35.2% to 25.9%). The distribution of centre-level

TABLE 2 PATIENT AND EMBRYOLOGICAL CHARACTERISTICS BEFORE AND AFTER AUDIT IMPLEMENTATION

Characteristic	Total number (*n*)	Before audit implementation (*n*)	After audit implementation (*n*)
Number of patients	34,461	17,280	17,181
MII oocytes retrieved	500,019	247,259	252,760
Blastocysts	256,769	118,094	138,675
Good-quality blastocysts[a]	147,030	73,287	73,743

[a] Good-quality blastocysts were defined as those graded >3BB according to the Gardner and Schoolcraft criteria.

MII, metaphase II.

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TABLE 3 EMBRYOLOGY LABORATORY PERFORMANCE PARAMETERS BEFORE AND AFTER IMPLEMENTATION OF THE AUDIT PROGRAMME ACROSS THE 30 CENTRES

Outcome	Audit phase[a]	Mean ± SD (%)	95% CI (%) (of mean)	Mean difference (%) (95% CI)	*t*-value (df)	*P*-value
Compliance rate[b]	Pre-audit	74.4 ± 7.6	(71.5–77.1)	5.7 (2.2–9.3)	3.4 (29)	0.002
	Post-audit	80.1 ± 7.8	(77.2–83.0)			
Blastocyst rate[c]	Pre-audit	51.2 ± 7.6	(48.3–54.0)	5.2 (2.8–7.6)	4.4 (29)	<0.001
	Post-audit	56.5 ± 8.2	(53.3–59.5)			
Good-quality blastocyst rate[d]	Pre-audit	31.3 ± 5.0	(29.5–33.2)	0.4 (-1.5 to 2.2)	0.41 (29)	0.679
	Post-audit	31.7 ± 6.1	(29.5–34.0)			
Biochemical pregnancy rate[e]	Pre-audit	72.3 ± 6.5	(69.9–74.7)	3.4 (1.3–5.3)	3.4 (29)	0.002
	Post-audit	75.7 ± 4.8	(73.9–77.5)			

Statistical analysis was performed using paired *t*-test.

[a] The pre-audit and post-audit phases are the time periods before and after the implementation of auditing, respectively, for the blastocyst, good-quality blastocyst and biochemical pregnancy rates. The pre-audit compliance rate is that calculated at the first audit, while the post-audit compliance rate is that calculated at the second audit.

[b] The compliance rate was calculated as: (sum of the scores for complete compliance, partial compliance and non-compliance ÷ 1490) × 100.

[c] The blastocyst rate was calculated as the percentage of blastocysts formed among metaphase II oocytes injected with spermatozoa.

[d] The good-quality blastocyst rate was calculated as the percentage of good-quality blastocysts (defined as grade >3BB according to the Gardner and Schoolcraft criteria) formed among metaphase II oocytes injected with spermatozoa.

[e] The biochemical pregnancy rate was calculated as the percentage of embryo transfers that resulted in a biochemical pregnancy (defined as a β-human chorionic gonadotrophin concentration >25 IU/l detected via maternal blood testing).

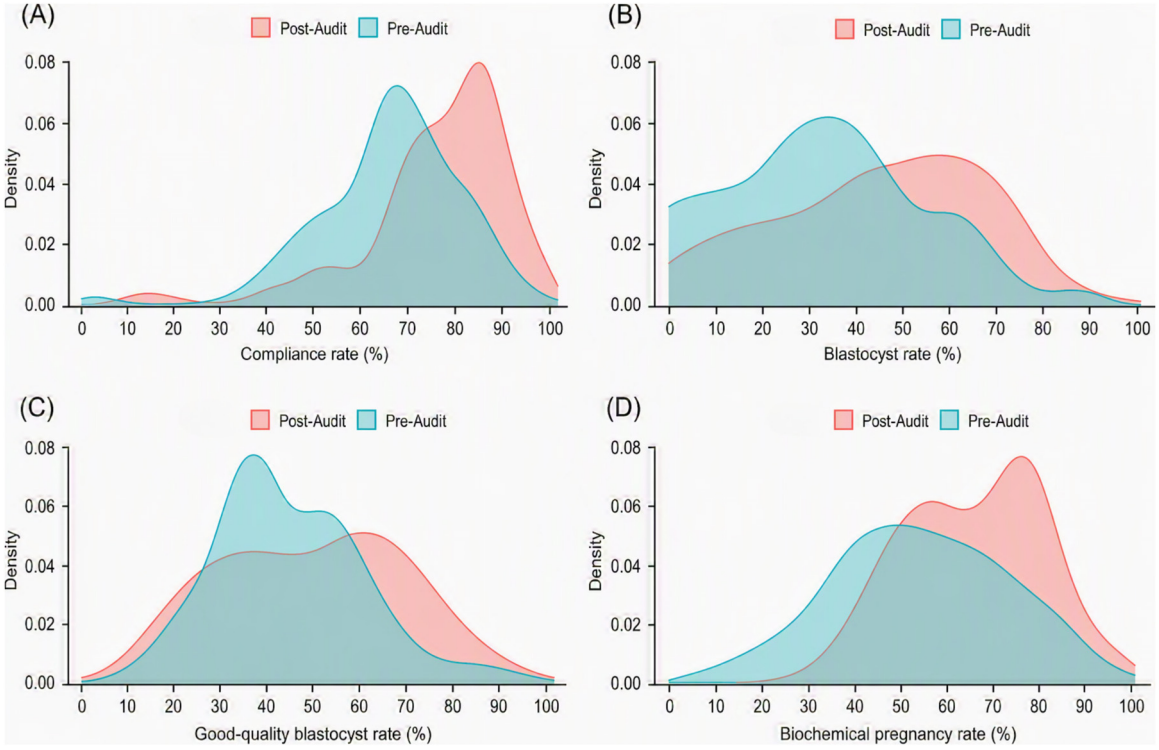


FIGURE 5 Density plots comparing the distribution of laboratory and clinical outcomes pre- and post-audit. (A) Compliance rate, (B) blastocyst rate, (C) good-quality blastocyst rate, and (D) biochemical pregnancy rate in the pre-audit and post-audit phases at the 30 centres. The compliance rate (%) was calculated as: (sum of the scores for complete compliance, partial compliance and non-compliance ÷ 1490) × 100. The blastocyst rate was defined as the percentage of blastocysts among the total number of metaphase II oocytes inseminated. The good-quality blastocyst rate was defined as the percentage of good-quality blastocysts (defined as grade >3BB according to the Gardner and Schoolcraft criteria) among the total number of metaphase II oocytes inseminated. The biochemical pregnancy rate was defined as the percentage of embryo transfers that resulted in a biochemical pregnancy (defined as a β-human chorionic gonadotrophin concentration >25 IU/l detected via maternal blood testing). The pre-audit and post-audit phases are the time periods before and after the implementation of auditing, respectively, for the blastocyst, good-quality blastocyst and biochemical pregnancy rates. The pre-audit compliance rate is that calculated at the first audit, while the post-audit compliance rate is that calculated at the second audit.

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good-quality blastocyst rates pre-audit and post-audit is depicted in Supplementary Figure 3.

Biochemical pregnancy rate

The mean ± SD biochemical pregnancy rate improved significantly from 72.3% ± 6.5% pre-audit to 75.7% ± 4.8% post-audit ($P = 0.002$) (TABLE 3 and FIGURE 5D). Centre-level analysis (Supplementary Table 6) showed that 23 of 30 centres achieved higher rates post-audit, with the greatest increases observed in Centre C (increase of 19.9% from 58.8% to 78.7%) and Centre U (increase of 14.2% from 64% to 78.2%). Seven centres had modest declines, with the largest decrease in Centre H (decrease of 4.6% from 77.0% to 72.4%). The centre-level distribution of biochemical pregnancy rates pre-audit and post-audit is demonstrated in Supplementary Figure 4. The overall dot-plot distributions of all the outcomes are illustrated in FIGURE 6.

DISCUSSION

To the best of the authors' knowledge, this is one of the largest investigations demonstrating the impact of a systematic internal audit system on embryological and clinical outcomes in IVF laboratories. The implementation of audit and quality management protocols resulted in marked improvements in compliance rates and laboratory outcomes. This upward trend reflects strict adherence to SOP, workflow efficiency, and standardization of the organization. However, in some of the centres, there was no improvement in compliance rates, particularly where there were pre-existing high performance and compliance with operational SOP. Although a subset of centres showed comparatively less extensive improvements after the audit, their outcomes consistently remained above the institutional competency level. In conjunction with these developments, the programme also integrated the implementation and digitalization of KPI monitoring, EWS, alarm and monitoring system, and establishment of internal benchmarks. This work indicates that a collaborative and structured framework is particularly effective at uplifting mid- and lower-performing laboratories while harmonizing quality standards across the network.

A recent publication by *Alikani and Campbell (2025)* described the persistent variability in IVF laboratories, and the opportunities and methods required to propel standardization forwards. They highlighted the benefits of data-driven benchmarks, process automation, and quality management to achieve more predictable outcomes. Published consensus statements and professional guidelines consistently emphasize the importance of standardization and quality management in IVF laboratories; however, they do not explicitly address the operational complexities inherent to large corporate or network-based laboratory models. This study highlights this gap by evaluating the implementation and impact of a structured audit framework within a large corporate IVF clinic chain. *Sakkas et al. (2018)* highlighted the importance of recording and tracking non-conformities observed according to ISO 15189 principles (*Schneider et al., 2017*), depicting how systemic documentation fosters a culture of traceability and continuous improvement. They emphasized that errors are an inherent and unavoidable component of IVF practice, underscoring that no laboratory is immune to procedural deviations. Importantly, their work reinforced the need for robust systems dedicated to the identification, documentation and analysis of errors, positioning error reporting, not as a marker of poor performance, but as a

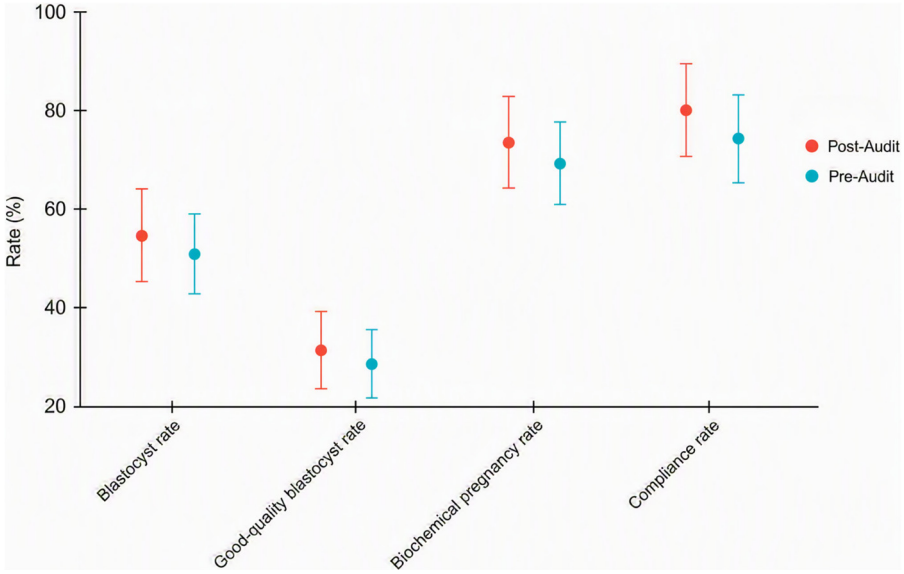


FIGURE 6 Dot plots comparing laboratory and clinical outcomes pre-audit and post-audit. Dot plot illustrating the mean ± SD biochemical pregnancy rate, blastocyst rate, compliance rate, and good-quality blastocyst rate in the pre-audit and post-audit phases among the 30 centres. The biochemical pregnancy rate was the percentage of embryo transfers that resulted in a biochemical pregnancy (defined as a β-human chorionic gonadotrophin concentration >25 IU/l detected via maternal blood testing). The blastocyst rate was the percentage of blastocysts that developed among metaphase II (MII) oocytes inseminated via intracytoplasmic sperm injection (ICSI). The compliance rate (%) was calculated as: (sum of the scores for complete compliance, partial compliance and non-compliance ÷ 1490) × 100. The good-quality blastocyst rate was the percentage of blastocysts graded as >3BB according to the Gardner and Schoolcraft criteria among MII oocytes inseminated via ICSI. The pre-audit and post-audit phases are the time periods before and after the implementation of auditing, respectively, for the blastocyst, good-quality blastocyst and biochemical pregnancy rates. The pre-audit compliance rate is that calculated at the first audit, while the post-audit compliance rate is that calculated at the second audit.

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fundamental requirement for strengthening laboratory governance and patient safety.

Correspondingly, the recently published consensus report (*Cairo Consensus Group and Alpha Scientists in Reproductive Medicine 2025*) emphasized that laboratory accreditation and quality management acts as a cornerstone for future-proofing IVF practices, whilst outlining the need for global strategies to standardize quality assurance and enhance governance across laboratories. The consensus highlighted the need for globally harmonized strategies to standardize quality assurance and strengthen laboratory governance across diverse clinical settings. By articulating foundational principles of laboratory accreditation, the authors provided a flexible yet robust framework that can be adapted by individual centres to support sustained quality, safety and regulatory preparedness in evolving IVF landscapes. Additionally, *ESHRE Special Interest Group of Embryology and Alpha Scientists in Reproductive Medicine (2017)* further recommended standardized KPI, performance indicators and reference indicators as measurable benchmarks to assess, monitor and augment assisted reproductive technology laboratory performances, and the joint Italian Society of Fertility and Sterility and Reproductive Medicine and Italian Society of Embryology, Reproduction and Research consensus (*Vaiarelli et al., 2023*) also emphasized the importance of continuous monitoring, operator evaluation and harmonization for laboratory performance. *Vaiarelli et al. (2023)* further validated the Vienna consensus by providing real-world benchmarks such as blastocyst development rate, clinical pregnancy rate and multiple pregnancy rate. Moreover, *Fabozzi et al. (2020)* demonstrated effective measures of evaluating KPI in embryology laboratories, highlighting the structural and procedural ways to track staff performances and their influence on the clinical outcomes. Importantly, the study illustrated that well-defined KPI translate complex laboratory activities into measurable quality signals, enabling proactive governance, accountability and sustained performance optimization. These consensuses highlight the importance of quality management, and emphasize that every laboratory should include their own system according to their equipment and processes, as demonstrated in FIGURE 7. Therefore, this investigation aimed to develop a sophisticated and robust system of audit and inspection with transparent KPI monitoring and benchmarking to accomplish network-wide standardization.

This research reinforces the value of such international frameworks by demonstrating that structured internal audits can translate into real-world, large-scale IVF settings. Through standardized checklists, periodic assessments, and digitalized performance dashboards, audits ensure transparent KPI monitoring, error traceability, and prompt corrective action. Importantly, given that no external quality assurance tool for blastocyst grading existed and due to the inherent subjectivity in embryo assessment, a grading standardization and harmonization programme was implemented alongside the audit framework. Newly recruited embryologists underwent a structured training programme and competency assessment in a designated 'gold standard' laboratory prior to independent deployment to their respective centres. In addition, an institution-wide refresher initiative was conducted for all the embryologists, including a focused webinar on blastocyst assessment using the Gardner and Schoolcraft grading system (*Gardner and Schoolcraft, 1999*) and a mock assessment exercise to reinforce grading consistency. Standardized visual grading charts were also displayed at workstations to support real-time reference and uniform application of grading criteria. Collectively, these measures aimed to minimize interobserver variability and further strengthen the reliability of laboratory outcomes, and helped in strengthening the audit implementation programme. These approaches enabled procedural

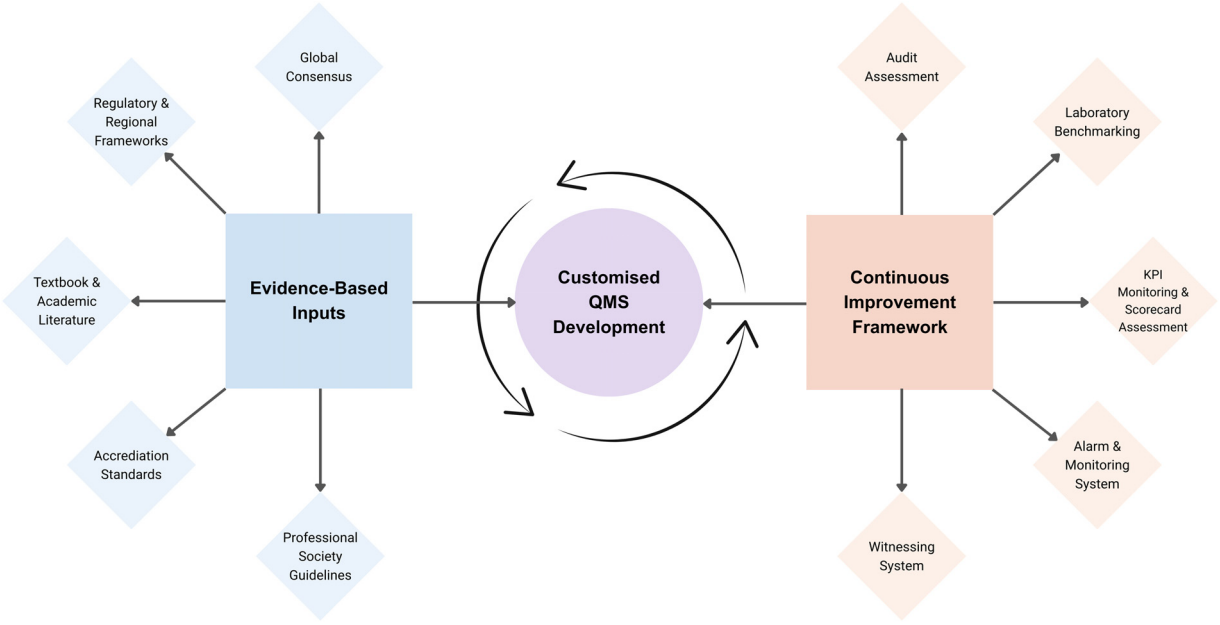


FIGURE 7 Conceptual framework illustrating the development of a customized quality management system (QMS) integrating international guidelines with continuous improvement strategies. KPI, key performance indicator.

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consistency and uniformity amongst the embryologists and laboratories, and boosted laboratory reproducibility.

By implementing auditing systematically in the network, the authors demonstrated that network-based IVF laboratories can achieve measurable gains in laboratory performance and outcomes, which may be transferrable to stand-alone centres. These insights extend existing literature by translating theoretical recommendations on quality governance into a practical, scalable and outcome-driven model. Over time, the audit process has evolved beyond a compliance tool to become an integral segment of good laboratory practice. In the authors' experience, following audit implementation, embryologists transitioned from viewing audits solely as a compliance exercise to a constructive mechanism for process improvements, fostering a culture of transparency and working with shared responsibility for the enhancement of laboratory outcomes. Such development of an audit system may be particularly effective for large IVF networks, where uniformity and benchmarking are paramount. Beyond the improvement of KPI, adoption of an internal audit system promotes patient safety, standardization, and regulatory readiness for external inspection or accreditation. With these foundations, audit acts beyond the scientific and managerial framework, strengthening clinical confidence, upholding compliance, and optimizing the quality of IVF care.

However, this research is subjected to certain limitations. The retrospective nature of this study may limit the ability to infer causality between audit implementation and embryological outcomes. Moreover, the influence of patient intrinsic factors and other variables on clinical outcomes cannot be controlled. As the study was conducted within a tertiary care setting, follow-up beyond biochemical pregnancy was not feasible. Additionally, the present analysis did not include all structural and process-related KPI. Future studies should evaluate the broader impact of standardization by incorporating these metrics alongside extended clinical outcomes, such as ongoing pregnancy and live birth rates, thereby providing a more comprehensive assessment of the long-term effects of audit-driven laboratory interventions.

Future research should aim to validate the sustained impact of audit implementation prospectively across multiple laboratory cycles and centres. This work represents an initial foundational step towards the development of scalable, checklist-driven audit frameworks that can be integrated systematically across large corporate IVF networks. The incorporation of digital audit innovations, including artificial-intelligence-driven analytics and predictive KPI modelling, holds promise for real-time performance tracking and early detection of deviation. Furthermore, future analyses should incorporate EWS-derived patient-safety indicators to better evaluate the impact of standardization initiatives on traceability, risk mitigation and patient safety. Comparative benchmarking of this audit framework with established international accreditation systems, such as the Reproductive Technology Accreditation Committee (*Fertility Society of Australia and New Zealand, n.d.*), Human Fertilisation and Embryology Authority (*Human Fertilisation and Embryology Authority, n.d.*), and ESHRE Quality Management Systems (*European Society of Human Reproduction and Embryology, n.d.*), could further strengthen its global applicability. Moreover, expanding this model to include diverse IVF settings, particularly in resource-limited environments, would assess its adaptability and scalability. Finally, evaluating the cost-benefit and clinical implications of audit-driven improvements may provide valuable insights into the long-term sustainability and clinical value of quality governance systems in reproductive medicine. Ultimately, these findings suggest that systematic quality management and structured internal audits can play a pivotal role in enhancing both laboratory performance and patient outcomes, laying the foundation for a new era of evidence-based quality assurance in IVF laboratories.

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AUTHOR CONTRIBUTIONS

Naval Shah: conceptualization, methodology, software, project administration, writing – review and editing, visualization. Vivek Dave: conceptualization, methodology, software, validation, project administration. Vipin Chandra: conceptualization, methodology, software, validation, project administration. Navneet Singh: methodology, investigation, writing – original draft, data curation. Babasaheb Ghodke: methodology, investigation, writing – original draft, data curation. Nitiz Murdia: conceptualization, software, supervision. Alison Campbell: writing – review and editing, visualization. Piyush Kakadiya: investigation, data curation. Jishnu PS: investigation, data curation. Satardu De: investigation, data curation. Ritesh Aggarwal: resources, project administration. Divreena Talwar: writing – original draft, visualization. Walmik Mistari: formal analysis. Anurag Chittora: data curation, formal analysis. Kshitiz Murdia: software, supervision.

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DATA AVAILABILITY

The datasets generated and analysed during the current study are available from the corresponding author on a reasonable request.

SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.rbmo.2026.105921.

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