FROM NEAR MISS TO NEVER AGAIN: TWO DECADES OF RISK MANAGEMENT AND ERROR PREVENTION IN AN IVF LABORATORY

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ABSTRACT

Objective: To evaluate 20-year outcomes of a structured quality improvement (QI) and risk-management program in a single IVF laboratory, with emphasis on never events, near misses, and longitudinal performance on predefined quality indicators (QIIs).

Design: Longitudinal, single-center quality improvement study (2004–2024).

Setting: Large healthcare network -affiliated IVF laboratory operating under CAP accreditation.

Patients/Cycles: 15,956 ART cycles (8,320 fresh IVF; 7,636 frozen embryo transfer).

Interventions: Implementation and continuous refinement of a laboratory QI framework comprising high-risk process mapping; QIIs with thresholds; standardized reporting (verbal escalation → SBAR); structured investigations (RCA) with corrective/preventive actions (CAPA); competency-based staff training; electronic/dual witnessing; cryoinventory reconciliation; equipment maintenance and alarm testing; and a non-punitive reporting culture.

Main Outcome Measures: Incidence of never events and intercepted near misses; protocol non-compliance; report errors; cryoinventory accuracy (QIR07); gamete/embryo traceability (QIR10); equipment/handling issues affecting care (QIR16).

Results: Across 20 years, one true “never event” occurred (erroneous discard of an embryo intended for cryopreservation with freezing of a lower-quality embryo instead; ≈0.006% of cycles). The event was disclosed, investigated via RCA, corrected per SOPs, and remediated with a no-cost IVF cycle. One intercepted near miss (thaw of an undesired-gender embryo detected pre-transfer) was identified, disclosed, and resolved (refreeze and correct embryo transfer) without clinical impact. Protocol non-compliance declined from 8 cases (2004) to 0 by 2008 and remained at or near zero thereafter. Report errors decreased to 0% in recent years. Cryoinventory performance remained near 0% error with one easily resolved misplacement. Gamete/embryo traceability (QIR10) stayed well below thresholds with no significant missing/untraceable specimens. QIR16 recorded one handling incident (faulty pipette), causing loss of several oocytes, prompting protocol revision, equipment checks, and retraining via RCA/CAPA.

Conclusions: A structured, data-driven QI program–embedding SBAR, RCA/CAPA, traceability safeguards, and a just culture–was associated with sustained near-zero serious events and progressive reliability gains over two decades. This reproducible model can inform benchmarking and multi-center learning aimed at further reducing latent risk in IVF laboratories.

Keywords: In vitro fertilization (IVF) laboratory; Quality improvement (QI); Patient safety; Never events; Root cause analysis (RCA); Corrective and preventive actions (CAPA); Specimen traceability and cryoinventory.

Introduction

In vitro fertilization (IVF) is a highly complex medical process that requires seamless coordina-tion between the clinical, surgical, and laboratory components of care.[1,2] The success of an IVF cycle hinges not only on advanced medical and embryological techniques but also on the precision, vigilance, and reliability of each team involved. Within the IVF laboratory in particu-lar, stringent procedural controls and quality assurance measures are essential to prevent er-rors that, while rarely life-threatening, can have profound emotional and clinical consequenc-es for patients.[1] In this paper, we present our experience implementing a robust internal risk management and error prevention program at a single IVF center over a 20-year period. We describe the evolution of our systems, the types of nonconformances encountered, and the strategies that proved most effective in fostering a culture of safety, accountability, and continuous improvement.

Materials and Methods

In compliance with the College of American Pathologists (CAP) laboratory accreditation standards, our IVF laboratory established a comprehensive Quality Improvement (QI) program aimed at identifying, monitoring, and mitigating risks throughout all phases of laboratory operations.[3,4] A key component of this initiative was the systematic identification of high-risk process steps where nonconformances were most likely to occur, and the mapping of performance indicators to those steps.[2]

For each identified risk point, we developed corresponding Quality Improvement Indicators (QIIs) and established predefined threshold limits, informed by historical performance metrics, clinical significance, and regulatory guidance.[2–4] These QIIs served as measurable benchmarks for ongoing monitoring and quality assessment. A complete list of QIIs and their respective thresholds is provided in Table 1.

Nonconformances were broadly defined to include, but not be limited to, documentation errors, specimen mislabeling, procedural deviations, equipment failures, and any departure from standard operating procedures (SOPs). The reporting process began with an immediate verbal notification to the supervisor or laboratory director, followed by discussion during the daily laboratory huddle.

Following this, a written SBAR (Situation, Background, Assessment, Recommendation) report was submitted by the staff member involved.[5] When necessary, a structured root cause analysis (RCA) was conducted to understand the underlying factors contributing to the event fully and to guide the development of appropriate corrective and preventive actions (CAPA).[6] All nonconformance reports were logged into a centralized database (Figure 1) and reviewed during regular laboratory meetings. Staff were trained to report all deviations in a non-punitive environment, reinforcing a culture of transparency, safety, and continuous improvement.[6]

Nonconformance incidents were tracked and plotted on a monthly basis, allowing for trend analysis and early detection of recurring issues. The effectiveness of the QI program was evaluated annually by comparing current data against the laboratory's historical benchmarks, in alignment with CAP accreditation requirements.[3,4]

Additionally, "never events" were defined as serious, clearly identifiable, and largely preventable incidents that compromise patient identity, consent, genetic parentage, or the integrity of gametes/embryos–i.e., events that must not occur if clinic systems and controls are function-ing as designed (Table 2).[7,8]

Results

In the interest of brevity, we present a sample of key performance indicators observed over the study period.

Never Events:

Over the course of 20 years, our program performed 8,320 fresh IVF cycles and 7,636 frozen embryo transfer (FET) cycles. Within this period, two significant adverse events were documented.

1) True Never Event

Incident: An embryo intended for cryopreservation was erroneously discarded, while a lower-quality embryo was frozen in its place.

Response: A full Root Cause Analysis (RCA) was conducted in accordance with established SOPs. Corrective actions were implemented, and the affected patient was offered a repeat IVF cycle at no cost.

2) Intercepted Never Event

Incident: An embryo of an undesired gender was mistakenly thawed.

Response: The issue was identified prior to embryo transfer. The patient was immediately informed, the embryo was refrozen, and the correct embryo was thawed and transferred without clinical impact.

Quality Indicators (2004-2024):

One of the most impactful trends observed was the elimination of protocol non-compliance. Specifically, the number of documented deviations from laboratory protocols decreased from 8 cases in 2004 to 0 by 2008, remaining at or near zero thereafter (Figure 2).

Report accuracy improved steadily due to safeguards including routine audits, dual-signature protocols, structured proofreading, and electronic verification systems, reaching 0% documented errors in recent years (Figure 3).

Cryopreserved specimen tracking (QIR07) performed near 0% error across the period; one misplaced specimen was rapidly identified and resolved without patient impact, supported by labeling, reconciliation audits, dual-operator verification, and secure tank mapping.

Gamete/embryo traceability (QIR10) remained well below thresholds with no significant missing or untraceable specimens, supported by chain-of-custody controls, redundant witnessing, periodic audits, and cryostorage reconciliation.

Technical difficulties with equipment or handling (QIR16) included a single incident caused by a faulty pipette, resulting in the loss of several oocytes. This incident prompted protocol revisions, equipment checks, and retraining, which were executed via RCA/CAPA.

Overall, quality indicators remained low throughout the 20-year study period and either improved or remained at predefined acceptable thresholds.

Discussion

Principal findings

Over 20 years and 15,956 ART cycles, a structured QI program–anchored in proactive monitoring, standardized reporting (verbal notification → SBAR → RCA → CAPA), and a non-punitive safety culture–was associated with sustained low rates of nonconformance and continued im-provement across key indicators.[2,3,5,6,12] Only one true never event occurred (erroneous discard of an embryo intended for cryopreservation with freezing of a lower-quality embryo instead), and one intercepted near miss was identified before reaching the patient (thaw of an undesired-gender embryo detected pre-transfer).[7,8]

Interpretation

In IVF, where errors can carry profound emotional, ethical, and legal consequences despite rarely threatening physical safety, the bar for identity verification, documentation integrity, and specimen traceability is uniquely high.[1,7] The elimination of protocol noncompli-ance within four years, the decline of report errors to zero, and near-zero rates for cryo-inventory and traceability issues suggest that program controls reduced latent system risk.[1–3,9–11] The single handling incident linked to a faulty pipette demonstrates how isolat-ed events can catalyze durable system improvements (protocol revision, equipment checks, retraining).[6]

Key program elements

Outcomes likely reflect: (1) early identification of high-risk steps; (2) clearly defined QI indicators with explicit thresholds; (3) immediate, standardized response workflows (verbal escalation, SBAR, RCA, CAPA); (4) routine trend review with feedback to staff; (5) a just culture that encourages reporting; and (6) visible leadership engagement.[2–6,12]

Strengths and limitations

Strengths include the long observation period, consistent definitions of nonconformance, and closed-loop corrective actions. Limitations include the single-center design, potential under-reporting bias inherent to incident-driven systems, and evolving case mix, technology, and staffing over two decades that may confound temporal trends. Thresholds were tailored to local risk tolerance and may require calibration before external adoption.[2–4]

Implications for practice

Embedding QI into day-to-day operations–rather than treating it as a periodic audit–appears essential. Laboratories seeking similar outcomes should prioritize identity-check redundancy, cryoinventory reconciliation, structured documentation reviews, and rapid RCA/CAPA cy-cles; electronic or automated witnessing can support efficiency and reduce risk.[1,2,9–11] Patient-centered transparency (including timely disclosure and remediation) is both ethically imperative and operationally clarifying.[7]

Future directions

Multi-center collaborations using harmonized indicators, electronic witnessing/traceability analytics, and prospective evaluation of near-miss data could refine benchmarks and acceler-ate learning across programs.[2,9–11]

Summary

Across two decades, a robust, data-driven quality management program in a single IVF laboratory was associated with one true never event, one intercepted near miss, and sustained improvement of critical metrics–protocol non-compliance to zero, report errors to zero in recent years, and near-zero rates for cryoinventory and traceability issues–while a single handling inci-dent prompted comprehensive protocol and training reforms.[1–3,6–11] These results support a reproducible model in which measurable indicators, timely reporting, structured RCA/CAPA, and a supportive safety culture jointly uphold patient safety and the integrity of IVF processes.

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Table 1. IVF laboratory QI program: Quality indicators, thresholds, and corrective actions

Quality Indicator	Threshold	Corrective action
QIR01 – Lab protocol non-compliance (including near misses) (# non-compliance / # ART procedures × 100%)	0%	SBAR; +/- direct observation; RCA; Implementation as needed
QIR02 – Laboratory communication issue	≤3 episodes/month	SBAR; RCA; Implementation as needed
QIR03 – Consent issue (incomplete, missing info/ form)	≤2 episodes/month	SBAR; RCA; Implementation as needed
QIR04 – Requisition form issue (incomplete, missing info/ form)	≤2 episodes/month	SBAR; RCA; Implementation as needed
QIR05 – Error in released report (# occurrence / # ART procedures × 100%)	<5%	SBAR; RCA; Implementation as needed
QIR07 – Cryoinventory issue (e.g., missing or misplaced specimens)	0%	SBAR; RCA; Implementation as needed
QIR08 – Scheduling issue affecting or potentially affecting patient care	0%	SBAR; RCA; Implementation as needed
QIR09 – Chain of custody not documented	0%	SBAR; RCA; Implementation as needed
QIR10 – Missing eggs / embryos (# missing / # handled × 100%)	≤2%	SBAR; RCA; Implementation as needed
QIR13 – Incomplete forms / document control issue by the clinic	≤3/month	SBAR; RCA; Implementation as needed
QIR14 – Incomplete forms by MD	≤3/month	SBAR; RCA; Implementation as needed
QIR15 – Incomplete forms by IVF lab	≤3/month	SBAR; RCA; Implementation as needed

QIR16 – Technical issue affecting laboratory procedure (e.g., oocytes stuck in stripper; difficulty loading transfer catheter)	<2/month	SBAR; +/- direct observation; RCA; Implementation as needed
QIR17 – Procedure not performed as requisitioned	0%	SBAR; RCA; Implementation as needed
QIR20 – FDA compliance issue	0%	SBAR; RCA; Implementation as needed
QIR21 – Media/dish/chart preparation issue (near miss or actual problem)	0%	SBAR; +/- direct observation; RCA; Implementation as needed
QIR22 – QC procedure not performed per schedule/no corrective action performed	0%	SBAR; RCA; Implementation as needed
QIR23 – Identification and/or labeling issue	0%	SBAR; RCA; Implementation as needed
QIR24 – Report turnaround time not met	4 reports/month	SBAR; RCA; Implementation as needed
QIR25 – Equipment failure affecting culture system	0%	SBAR; RCA; Implementation as needed
QIR26 – HIPAA issue (patient confidentiality)	0%	SBAR; RCA; Implementation as needed
QIR27 – OSHA issues (workplace injury, biohazard/ chemical exposure, other safety concerns)	0	SBAR; RCA; Implementation as needed
QIR28 – Bacterial contamination of culture (from semen sample or other source)	0	SBAR; RCA; Implementation as needed
QIRC29 – Clinical/ASC issues that can affect laboratory/ outcomes	0	SBAR; RCA; Implementation as needed
QIRC30 – Complaints (patient/ physician/colleagues)	0	SBAR; RCA; Implementation as needed

Table 2. IVF laboratory QI program: Never Events and Corrective Actions

Never Event	Description	Corrective Actions (with RCA)
Wrong-patient / wrong-specimen use	Fertilization, insemination, culture, cryopreservation, thaw, or embryo transfer involving the incorrect gametes or embryos	1. Stop procedure immediately and secure specimens2. Notify laboratory and medical leadership immediately3. Inform affected patient(s) promptly4. Conduct urgent RCA and report to regulatory/ oversight bodies5. Revise SOPs, retrain staff, and strengthen identity-check systems
Procedure without valid consent	Any insemination, thaw, discard, transfer, or storage performed without documented and verified patient consent	1. Stop action immediately2. Notify laboratory and medical leadership immediately3. Inform patient(s) and disclose error4. Conduct RCA to identify gaps in the consent process5. Revise consent verification workflows and retrain staff
Irretrievable loss of gametes/embryos due to preventable error	Destruction or loss due to tank failure, ignored alarms, mislabeling, or incorrect warming/ handling	1. Secure and document affected material2. Notify laboratory and medical leadership immediately3. Inform patient(s) promptly4. Conduct RCA, including equipment/system review5. Update preventive maintenance protocols and retrain staff
Specimen released to the wrong recipient	Gametes or embryos given to the wrong patient, courier, or facility	1. Attempt immediate retrieval if possible2. Notify laboratory and medical leadership immediately3. Inform affected patient(s)4. Conduct urgent RCA and file regulatory reports as required5. Strengthen chain-of-custody and labeling SOPs and retrain staff

Inability to locate the cryopreserved specimen	Failure to find a stored gamete or embryo in the cryoinventory system (mislabeling, misplacement, or tracking error)	1. Suspend any planned procedures until resolved2. Notify laboratory and medical leadership immediately3. Inform affected patient(s)4. Conduct an urgent RCA and perform a full cryoinventory audit5. Improve reconciliation/ audit procedures and retrain staff
Patient's concerns about the parentage of a pregnancy or baby	A patient raises concern that a pregnancy or live birth may not be genetically theirs (suspected specimen mix-up or misattributed parentage)	1. Take concerns seriously and document in detail2. Notify laboratory and medical leadership immediately3. Inform compliance/risk management4. Conduct urgent RCA, offer genetic testing and counseling, and report if confirmed5. Strengthen identity verification and witnessing protocols

REPORT		JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC	threshold
QIR01	Lab protocol non-compliance issue (0)													0
QIR02	Lab - communication issue													<=3/month
QIR03	Consent issue (incomplete, missing info, missing form)													<=2/month
QIR04	Req. form issue (incomplete, missing info, missing form)													<=2/month
QIR05	Error in the released report													<5%
QIR07	Cryoinventory issue													0
QIR08	Scheduling issue													0
QIR09	Chain of custody not documented													0
QIR10	Missing eggs/embryos													<=2%
QIR13	Incomplete forms													<=3/month
QIR14	Incomplete forms by MD													<=3/month
QIR15	Incomplete forms by the IVF lab													<=3/month
QIR16	Technical issue													<2/month
QIR17	Procedure not performed as requisitioned													0
QIR20	FDA compliance issue													0
QIR21	Media, dish, chart prep issue													0
QIR22	QC procedure not performed per schedule/no													0
QIR23	ID and/or labeling issue													0
QIR24	QIR24 QI report – report turnaround time not met													<=4/month
QIR25	QIR25 QI report – equipment failure that affected the culture system													0
QIR26	QIR26 QI report – HIPAA issue													0

Figure 1. IVF laboratory QI program: Quality indicators, thresholds, and corrective actions

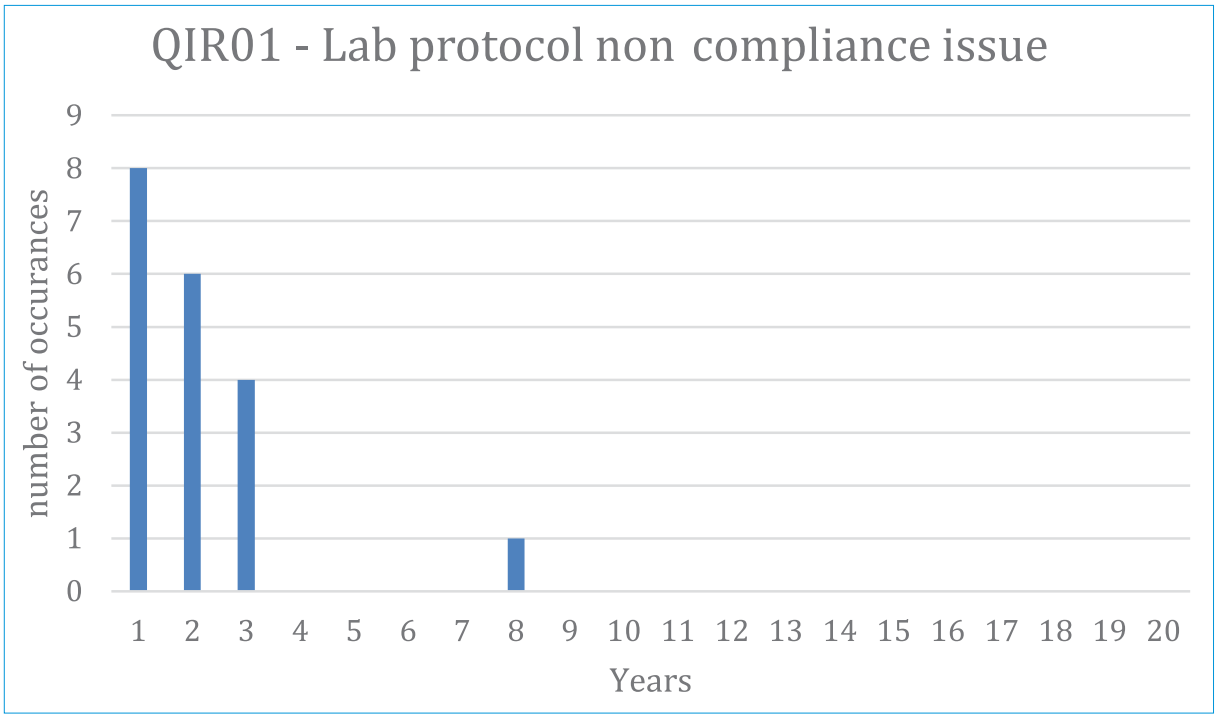

Figure 2. Performance of the QIR01 2004-2024

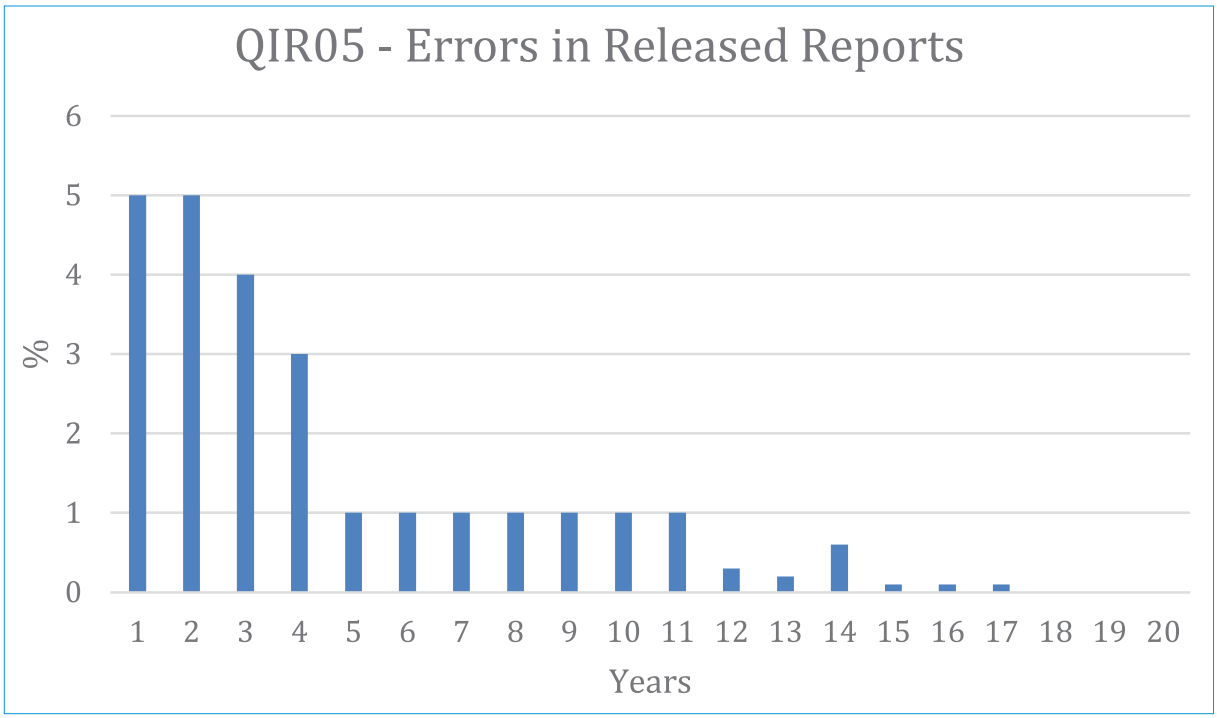

Figure 3. Performance of the QIR05 2004-2024