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Original Research Article

A Human Factors Approach to Discovering, Defining, and Co-Developing the Management of Critical Incidents in IVF Clinics

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Abstract:

Background: The regulation of In-vitro fertilization (IVF) clinics in the United Kingdom (UK) falls under the purview of The Human Fertilization and Embryology Authority (HFEA), an organization tasked with ensuring their adherence to both their code of conduct and the HFE Act of 2008 (HFEA, 2022; HFEA, 2021). To increase patient safety, each clinic is accountable for identifying errors, examining these incidents, and re-evaluating their procedures (HFEA, 2021). Incident reporting systems can be greatly improved by recognizing and resolving human factors.

Objective: To discover, define, and co-develop the management of critical incidents in IVF clinics from a human factors approach.

Methods: A preliminary study was conducted at Ninewells Assisted Conception Unit (ACU) to provide insights for the development of a survey comprised of open-ended and closed-ended questions. This online survey was sent out to healthcare personnel who are working in UK-registered IVF clinics and received responses from 48 healthcare personnel working in HFEA-registered IVF clinics. The acquired data was subjected to mixed deductive and inductive analysis and descriptive statistics. An interview was conducted one-on-one with ACU staff (6 participants). Document analysis was carried out respectively.

Results: IVF clinics are one of the most complex, multi-layered socio-technical systems in the health care sector, requiring a strategy that considers the system as a whole and understands the delicate balance of its functioning configuration. Incident management forms the foundation upon which patient safety can be ensured and progress in this field can be fostered. A key component of changing IVF clinics is incorporating Human Factors (HF) science for the benefit of society.

Conclusion: HFEA needs to introduce training on Human Factor (HF), a purpose-built reporting system, and encourage the whole team in participation of incident management competencies.

Keywords: Infertility, Human factors, assisted reproductive technology, Ergonomics.

Introduction

Fertility clinics in the UK play a crucial role in assisting individuals and couples who are facing difficulties in conceiving naturally. They offer a range of fertility treatments, with In Vitro Fertilization (IVF) and Assisted Reproductive Technology (ART) being the most common procedures. In Vitro Fertilization (IVF) is a fertility treatment where eggs are surgically retrieved from a woman's ovaries and fertilized with sperm in a laboratory.[1] After fertilization, the embryos are monitored for a few days, and then one or more healthy embryos are transferred into the woman's uterus to establish a pregnancy. Assisted Reproductive Technology (ART) is an umbrella term that encompasses various fertility treatments, including IVF, intrauterine insemination (IUI), egg donation, sperm donation, and surrogacy.[2] While fertility clinics in the UK are generally well-regulated, there have been some issues related to quality and safety in the sector. Some of the concerns include success rates, multiple pregnancies, impact on the emotion and psychology of couples, and high costs.[3]The Human Fertilization and Embryology Authority (HFEA) regulates fertility clinics to ensure legal and ethical standards are met through their Code of Practice (COP).[4] Legal guidelines for fertility clinics in the UK are provided by the Human Fertilization and Embryology Act 1990 and the HFE Act 2008.

They publish an annual report detailing adverse events at UK fertility clinics. The HFEA states clinics are required to have specific processes in place for reporting, investigating, and improving after more serious events, including appropriately amplifying information to HFEA.

In each authorized clinic, a "Person Responsible" (PR) is required by the HFE Act to monitor incident management and submit reports to the HFEA.[5] Human Factors (HF), or Ergonomics, is a multidisciplinary field that focuses on understanding the interaction between humans and their environment, tools, equipment, and processes. The goal of HF is to optimize systems, products, and processes to enhance safety, efficiency, and overall human well-being.[6] Some examples of HF are Specialists, Residents, House Officers, Trainee Doctors and Medical Associates, the Head of the laboratory, senior embryologists, junior/trainee embryologists, and lab assistants. The administrative team like quality manager, and the patients' family: patient, partners, close relatives, and kids.[5] The present study aims to discover, define, and co-develop the management of critical incidents in IVF clinics from a human factors approach.

Materials and Methods

The research received ethical approval from the University of Dundee, considering the project as a "Low risk" endeavour, according to research and governance policies. Prior informed consent was obtained from all participants in the online survey. The HFEA online clinic database was used to collect a full list of assisted conception units (ACUs) with their contact details. In cases where email addresses were not listed, websites were searched to find the appropriate contact information. Any staff member working within an ACU with relevant experience in incident reporting, investigation, and/or learning is included.

The online survey was created and conducted using Jisc. Invitations were sent to license ACUs across the United Kingdom, along with a patient data sheet, an explanation of the research purpose, and an online survey link. A total of 48 respondents giving informed consent were included in the study. The survey questionnaire was designed with a mixed structure of both open and closed-ended questions.

The closed-ended questions aimed to compare incident management processes and clinics directly, while the open-ended questions aimed to obtain a more profound understanding of participants' opinions about their work system, attitudes, and ideas for improvement using a HF approach. Data for this research was collected from multiple sources including the following forms [7-9] – Adverse Event Color Code sheet: This document provides predefined categories of adverse events classified as Red, Amber/Yellow, and Green events. Researchers will use this sheet as a reference for severity and type classification; QPulse Form: This form is an internal electronic reporting system that captures detailed information about each adverse event or near-miss occurrence in the healthcare facility. Data from this form will offer insights into individual incidents, immediate actions taken, and corrective and preventive measures implemented; the Datix Form: The Datix form is another reporting system that captures event details and response actions. Analyzing this form will provide additional context and complement findings from the QPulse form; and the HFEA Incident Report Form: This form contains information about adverse events specific to the Human Fertilization and Embryology Authority (HFEA). It will offer unique insights into incidents involving fertility treatments.

Statistical analysis:

Inferential statistics were used to analyze the closed-ended questions. Inferential statistics allowed for summarizing and organizing the data to find relationships between variables.[10] The thematic analysis was used to analyze the open-ended qualitative data collected from the respondents. The thematic analysis allowed for discovering and analyzing themes within the dataset, extracting rich sources of qualitative information. [11] The demographic analysis was done which aimed to understand how responses varied based on the department, experience, and designation of the respondents working in IVF clinics.

Results

Qualitative analysis: The qualitative data collected through interviews were thematically analyzed with the help of NVivo. The transcripts were coded, and the codes were categorized under relevant themes. Four major themes were derived from the analysis of the responses obtained from the participants: 1) Reporting Adverse Events; 2) Improving Reporting and Investigation Processes; 3) Learning from Adverse Events; 4) Implementation of Learning Points.[12] One participant noted that reporting adverse occurrences is simple and governed by a standard operating procedure (SOP) known as "SAP 08." The reporting procedure may be seen as time-consuming, and healthcare workers may struggle to find the time to complete the required documentation.

There is a special form that must be filled out to report adverse occurrences to the Human Fertilization and Embryology Authority (HFEA), and it may simply be emailed to them. The other participant noted that the quality manager aids in

the completion of the report by entering the required information and assuring correctness and completeness. The survey observed that Human Fertilization and Embryology Authority's (HFEA) standards for identifying significant adverse events are pretty clear. Clear and well-defined criteria help to shorten the reporting process and assure event categorization uniformity. One participant mentioned the difficulty of ensuring that changes to standard operating procedures, such as retraining and competency evaluation, are followed. It may be difficult to ensure that changes are implemented consistently, and assessing their efficacy is critical. The other participant indicated that executing changes involving different teams can be difficult. Different teams may have distinct needs and views, necessitating careful study to discover solutions that work for everyone.

Quantitative analysis:

The respondents of the analysis were grouped from various positions in different departments and denoted as Medical (A), Nursing (B), Laboratory (C), and Administrative (D). The majority of respondents were employed for the C roles. The reason for choosing these departments is A, B, C, and D departments are related departments that have much involvement, and it is related to the analysis title.

The experience of the respondents was denoted as familiar with the process (A), somewhat familiar with the process (B), not that familiar with the process (C), and uncertain about the process (D). About 67% of the respondents said that they had experience in each stage of the process, 26% of the respondents said that they had some experience in each stage of the process and 7% of the respondents said that they had no experience with the process. As a result, 100% of respondents have been involved in learning from a scenario. Figure 1 shows that about 57% of the respondents said that they had serious adverse events, 43% of the respondents said they had an adverse event and none of the respondents said that they were not aware of, near miss (NM) event. From series 2, it is clear that 70% of the respondents said that they had serious adverse event, 32% of the respondents said that they had an adverse event, and none of the respondents said that they were not aware of, NM event.

From series 3, it is clear that 76% of the respondents said that they had NM the event, 19% of the respondents said that they had an adverse event, 6% of the respondents said that they had a serious adverse event and none of the respondents said that they were not aware of the event. It was also found that 80% of respondents' said that if the employee don't report a NM it could be due to the uncertain event needed to be reported, 55% of respondents' said that if the employee don't report a NM it could be due to fear of blame, 51% of respondents' said that if the employee don't report a NM it could be due to lack of reporting culture, uncertain how to report or use the system, employee didn't think it was important, 45% of respondents' said that if the employee don't report a NM it could be due to don't think it will make much difference, 42% of respondents' said that if the employee don't report a NM it could be due to embarrassed to admit 32% of respondents' said that if the employee don't report a NM it could be due to forget to report, 29% of respondents' said that if the employee don't report a NM it could be due to unwanted professional repercussions and 19% of respondents' said that if the employee don't report a NM it could be due to would add work load, don't feel it's their responsibility.

Figure 2 shows that 73% of respondents' said that if the employee don't report an adverse event it could be due to fear of blame, 60% of respondents' said that if the employee don't report an adverse event it could be due to unwanted professional repercussion, 50% of respondents' said that if the employee don't report an adverse event it could be due to embarrassed to admit, 43% of respondents' said that if the employee don't report an adverse event it could be due to lack of open reporting culture, uncertain if event needed to be reported, 33% of respondents' said that if the employee don't report an adverse event it could be due to would add workload, uncertain how to report or use the system, 20% of respondents' said that if the employee don't report an adverse event it could be due to they don't feel it as their responsibility, forget to report and 13% of respondents' said that if the employee don't report an adverse event it could be due to they don't think it will make much difference, employee didn't think it was important.

Figure 3 shows that 37% of the respondents said the key benefits of scenario reporting helps to find the root cause of the error and make changes, 32% of the respondents said the key benefits of incident reporting improves safety for patients, embryos, and employee, 6% of the respondents said the key benefits of incident reporting encourages transparency and open culture in the team, 8% of the respondents said the key benefits of incident reporting help to identify patterns and trends and 1% of the respondents said all are benefits of incident reporting.

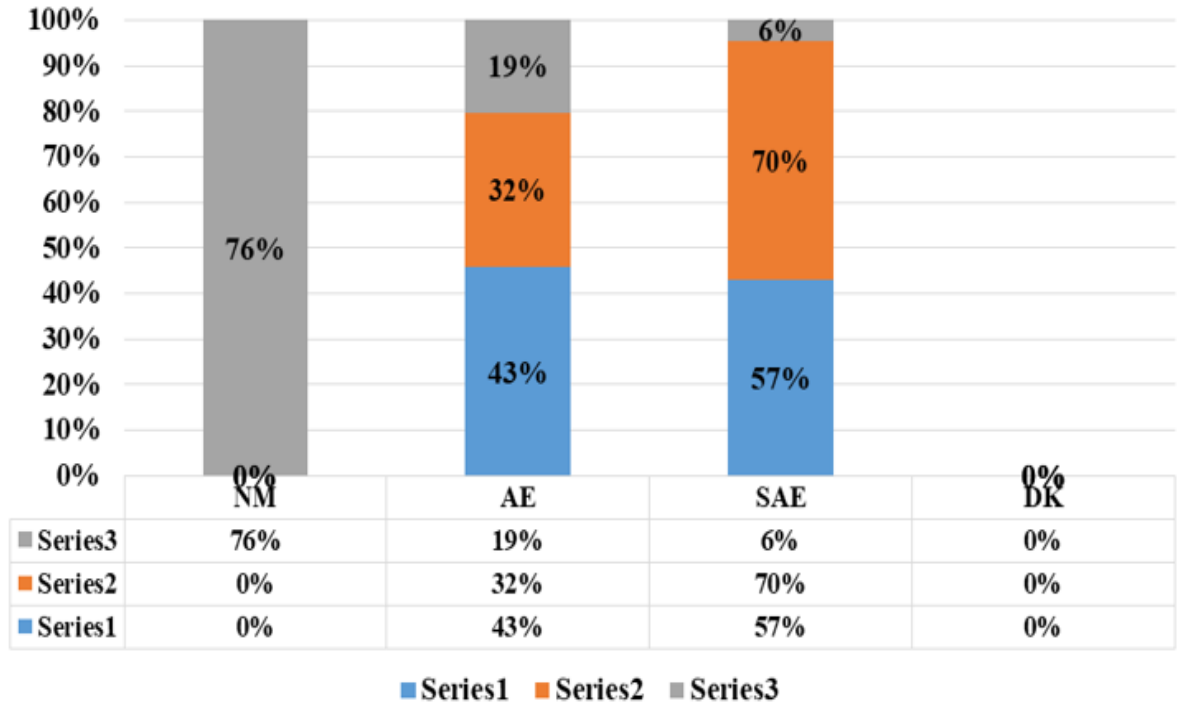

Figure 1: Comparison chart of one patient was mistakenly sent to the wrong recipient, affected the quality of a patients' embryos, mislabelled but identified before being used

Footnote: Series 1 denotes one patient was mistakenly sent to the wrong recipient, Series 2 denotes affected the quality of a patient's embryos, and Series 3 denotes mislabelled but identified before being used. NM: Near Miss; AE: Adverse event; SAE: Serious Adverse Event; DK: Don't Know

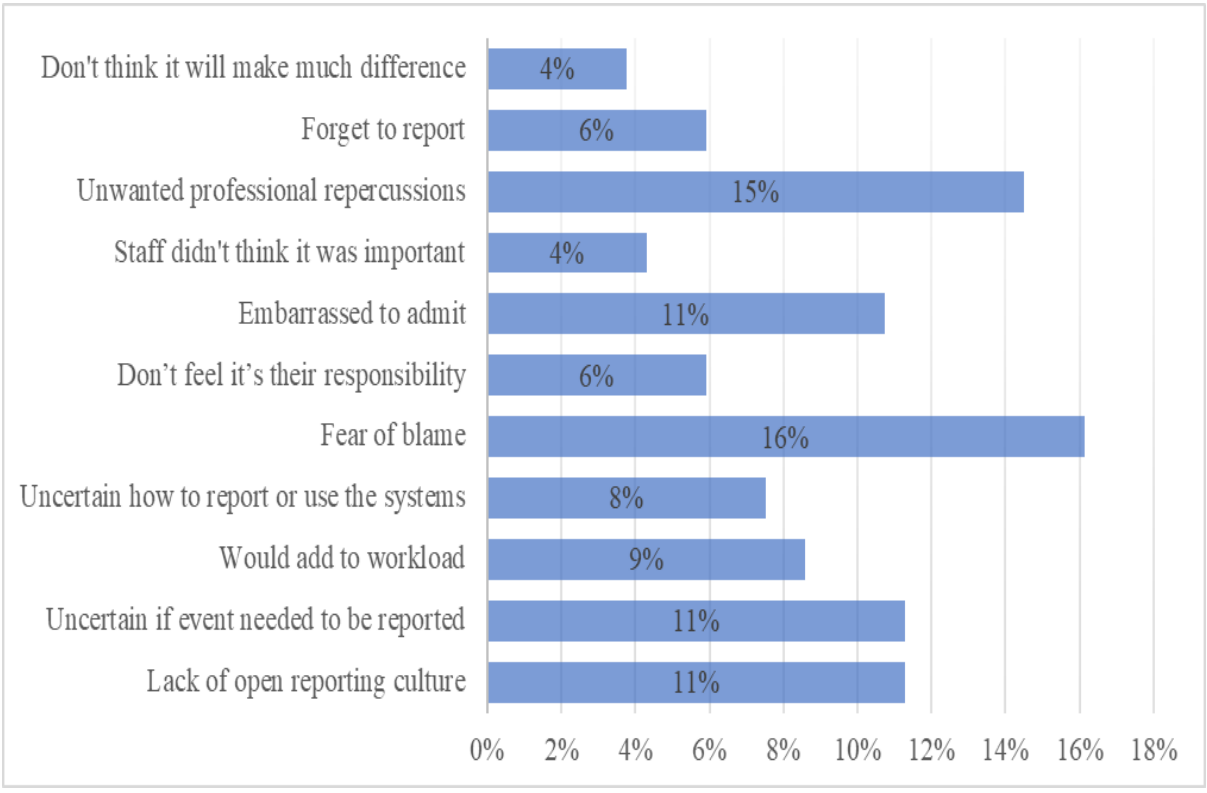

Figure 2: Bar chart showing reasons for not reporting an adverse event

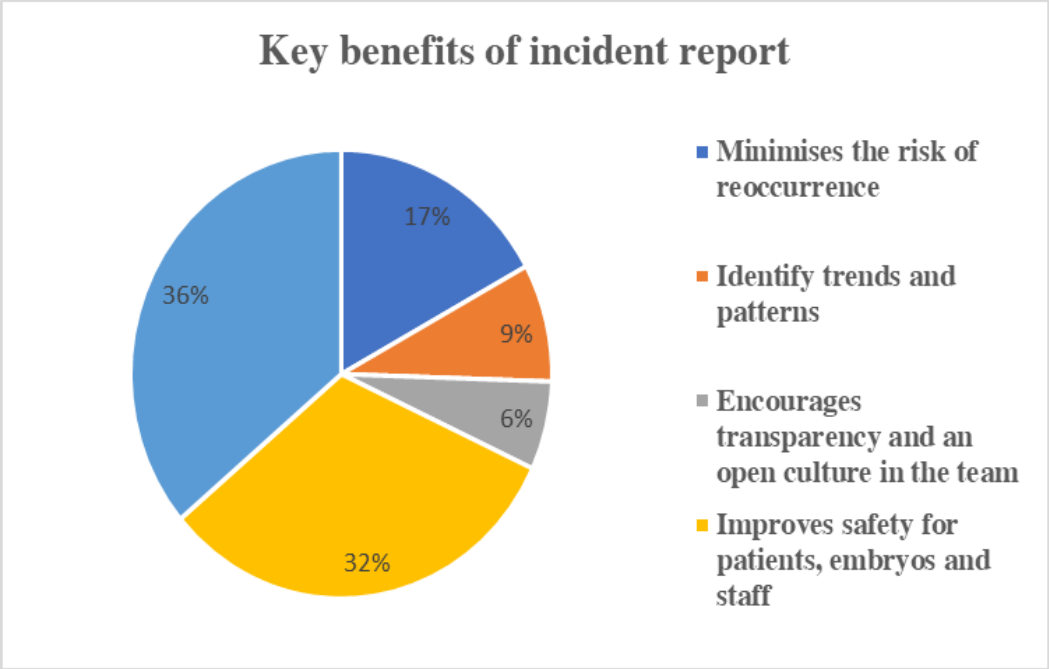

Figure 3: Pie chart showing key benefits of incident report

Discussion

In the analysis, it is evident that 80% of respondents cited "Uncertain if an event needed to be reported" as the reason for not reporting an adverse event in their department (Figure 2). Additionally, 75% of respondents were aware of the procedures for reporting an event. Sakkas (2018) has articulated a clear perspective on the requirements for patient safety practices [13]. The definition for the scenario was published by the Human Fertilisation and Embryology Authority, which operates independently and fails to coordinate with other regulatory authorities, such as group medical coverage; it primarily relies on the integration of various professionals to deliver a cohesive service [14].

In this research, only 67% of respondents understood how to report and investigate incidents in their department. Respondents indicated that the lack of awareness regarding the investigative process was attributable to work pressure, insufficient training, and a lack of encouragement or appreciation from management for employee efforts. Morini et al. (2021) noted that meaningful appreciation from the organization and the team can enhance employee effectiveness, allowing departmental requirements to be fulfilled promptly without perceiving tasks as burdensome [15]. Kerr (2009) asserted that if employees cannot participate in the investigative process, the quality of the investigation diminishes, which undermines the connections between employees and management.

Respondents expressed that the current investigation process requires further evaluation, suggesting that frequent meetings and proper follow-up could enhance its effectiveness [16]. From the analysis and literature review, it is clear that the tools and equipment utilized can serve as both obstacles and facilitators to work achievement. Sciorio (2022) noted that the necessary tools and resources were not provided to IVF departments, despite repeated regulatory requests for advancements to ensure optimal training [17].

Kerr et al. (2011) defined that collaboration within teams can foster improved productivity and culture; however, without effective communication and collaboration, unexpected challenges may arise, contributing to stress within departments. The analysis indicates that poor communication is a significant factor contributing to ineffectiveness [18].

In an IVF department, employees should collaborate on shared learning, supporting one another with their experiences, rather than leaving personnel to navigate challenges independently [19]. Enhanced communication can also reduce the likelihood of errors. The analysis revealed that poor communication is a prevalent reason for both near misses and adverse events. Rienzi et al. (2015) stated that groups within IVF departments work on various tasks while providing care for the same patients. If IVF teams can overcome communication barriers and effectively engage with the multiple professions involved within a single department, they can prioritize patient outcomes and develop a comprehensive understanding of the issues affecting the department [20].

The present study is not without limitations. Analysis shows majority of responders are in laboratory departments, with limited participation from medical, nursing, and administrative departments. IVF clinic incident management

systems require equal participation. Data from the QPulse Form, potential variations, and subjective categorization are limitations; inter-rater reliability checks will reduce bias.

Conclusion

Scenario management is crucial for patient safety and innovation, requiring employees to recognize mistakes, examine practices, and re-examine understanding to enhance patient amenities. Scenario management meetings address workplace challenges, learn from them, and communicate solutions. Improve reporting systems by raising employee awareness, restructuring software, and reducing time consumption; respondents struggle with workload, affecting reporting. Employee training and reviews improve scenario reporting, investigation, and learning outcomes. Lack of supervision and training in IVF departments risks harm.

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