EDITORIAL

Contemporary quality control in the IVF laboratory: heading to the cloud?

It has long been established that the successful operation of an IVF laboratory requires dedicated quality control and assurance, implemented at the appropriate level (*Mortimer and Mortimer, 2005*). In recent years we have witnessed increasing complexity within the clinical IVF laboratory, and, along with it an increasing demand on the laboratory staff to ensure optimal functioning of equipment and provisions to provide proper environmental conditions for gamete and embryo culture, striving to maximise the chances of conception and live birth. A persistent question remains in many practitioners' minds, however: What is an appropriate level of monitoring, and what is (are) the best way(s) to achieve it?

The paper by *Palmer and colleagues (2019)* in this issue of *RBMO* has gone some way to address this issue by comparing quality control data from 36 clinics across 12 countries, all of which used a cloud-based application for quality control monitoring. It was observed that there is heterogeneity in practices among laboratories, and, interestingly, that investment in quality control was substantial in countries in which accreditation of laboratories is required, while it was minimal in almost half of the laboratories surveyed.

It is evident that the reason we know comparatively little about quality control practices in assisted reproductive technology (ART) laboratories worldwide is that most of the data are buried in binders full of checklists and forms that at one time adorned clip boards or were taped to incubators, refrigerators and the like in the lab. The time and effort required for collation and analysis of data in this format has always been considerable, and usually beyond what is feasible for most clinics. As a result, although data are collected, they are rarely examined in detail apart from a monthly cursory review and acknowledgement. Thus, the development of a cloud-based application to collect, store, retrieve and analyse quality control data may be considered a natural progression. This is a logical and very practical approach, valuable to large and small clinics alike. Cloud-based quality management is standard in many mature industries such as aeronautical, automotive, pharmaceutical, food, and others; these are businesses that use quality control as a proactive and effective tool for improving performance. The report by *Palmer and colleagues (2019)* is in effect one of the first attempts to equip IVF laboratories with the technologies used elsewhere to great effect. This work therefore represents a novel approach and a 'call-to-action', though much remains to be done.

The call for standardization is logical but are we ready to define those standards? Although we now have tools that will allow for such an analysis, as yet we have not tied instrument performance to outcomes in a comprehensive manner, in a way that would make standardization evidence-based. Indeed, the report by Palmer does not relate any of the measured parameters to clinical outcome.

There remain a number of basic questions regarding quality control practices, specifically, whether we are measuring the correct parameters. This is especially perplexing given that there are at least 200 variables that can impact IVF outcome (*Pool et al., 2012*). Moreover, one could ask, are we taking measurements at appropriate frequencies? Are our measurement intervals catching important events like freezer cycling? Do we accept indirect measures, such as incubator CO_2, instead of biologically meaningful ones such as pH? We require further proof from transfer outcomes that temperature ranges must be narrow. Without this, we could be 'overdoing it' without meaningfully contributing to better outcomes; this could amount to wasting valuable laboratory resources. Hence, an advantage that emerges from the use of such a cloud-based system is that data sharing may assist in the fine-tuning of such ranges and help to optimise those parameters linked to clinical outcome. Further studies are required to help ascertain key parameters and the frequencies of monitoring, which will vary depending on the parameter in question.

In its classical usage, quality control in the IVF laboratory is simply documentation to show that equipment and instruments are functioning and doing so within a predetermined range of operational parameters tied to the analytical phase of a testing event. That proof is then archived either physically in binders or electronically on a server where it remains dormant, unless retrieved for accreditation purposes. Cloud storage and tools to rapidly deposit and retrieve quality control data for any instrument over any specified time interval with simply a few keystrokes changes all of that. The timely discovery of faulty equipment/instrumentation followed by immediate corrective actions through effective quality management practices is the gold standard of quality control; however, the potential linking of quality control performance to enhanced patient care and outcomes without opening a binder or spreadsheet suggests that the cloud may truly possess a silver lining.

REFERENCES

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