

## Reply: Performance indicators in ART: time for a reappraisal?

Sir,

We appreciate your interest in our article detailing the development of performance indicators (PIs) for clinical practice in ART (Vlaisavljevic *et al.*, 2021) and your comments.

PIs are objective measures for evaluating critical healthcare domains (patient safety, effectiveness, equity, patient-centeredness, timeliness and efficiency). In the setting of an ART laboratory and clinic, quality indicators are necessary for systematically monitoring and evaluating laboratories' and clinics' contributions to patient care (ISO15189-2012) and they represent an important element within the Quality Management System (De los Santos *et al.*, 2016). Very practically, PIs are to be used and monitored within a laboratory/clinic to act upon fluctuations. In case of dropping PIs, the clinic should find the root causes and remediate them. Similarly, in the case of rising PI values, the reasons for the improvement should be investigated and attempts should be made to maintain the improved process.

The commentator states that 'the final goal of ART should be the birth of a healthy baby for a couple who struggles with that'. We could not agree more and, in fact, we stated in our paper that 'A singleton live full-term healthy baby is the most relevant standard of success in ART' (Min *et al.*, 2004). There is not much debate regarding the use of live birth rate (LBR) for evaluating interventions. In our paper, however, LBR was investigated as a PI and was found to be non-efficient for monitoring daily clinical practice, whereas clinical pregnancy rate (CPR) was. Following confirmation of clinical pregnancy after ART, any adverse outcome that will not lead to live birth is unlikely to be associated with the performance of the clinician or the lab. On top of that, CPR offers the possibility to react more quickly in performing root-cause analyses. Even if a relevant standard of success and an important parameter in registries, LBR is not the best indicator to be monitored for quality management in an ART centre.

The commentator further comments on the definition of a reference population for PI monitoring, defined as female patients <40 years old, using own fresh oocytes, ejaculated spermatozoa (fresh or frozen), any insemination method (i.e. routine IVF and ICSI) and no preimplantation genetic testing. The commentator specifically refers to the exclusion of patients above 40 years old, stresses the importance of female age on the outcomes of ART procedures and cycles and suggests bringing the PI estimation back to the 'real world'. Referring to the explanation above of the aim and use of PIs, it is reasonable, as for laboratory key performance indicators (KPIs), to limit fluctuations from variability in the population treated and improve the accuracy of the PI estimation by applying a reference population. It is because we acknowledge the impact of female age on the different PIs that a

reference population was defined. The same reference population cited in the Vienna consensus was chosen for the Maribor consensus paper as centres would like to relate laboratory PIs to clinical PIs. The group did provide indicators related to poor, normal or high responders making it possible to calculate indicators regardless of age. The age criterion in the definition of the reference population may be revised in the future, possibly aided by algorithms that take into account a lot more variables. Machine learning approaches will be able to analyse a lot more data, follow trends in real-time and alert clinics when deviations are starting to appear.

Finally, the commentator refers to the blastocyst transfer and single embryo transfer (SET) rates, stating that both parameters should have been included as PI. Blastocyst transfer is a strategy that a centre may adopt and take into account when evaluating PIs but it cannot be used to evaluate performance within a centre. We do acknowledge the value of SET as a marker of good clinical practice. It is a relevant strategy, but on the other hand, we also consider that it is currently largely dependent local legislation and couple's decisions. ESHRE is preparing an evidence-based guideline on embryo transfer, which will support SET as embryo transfer strategy and the recommendation that it will be included in a future update of the defined PIs.

In conclusion, we would like to emphasize that the proposed list of PIs represents the minimum standard that gives clinics a tool to monitor the clinical performance and to implement if needed, corrective measures. PIs are often related to quality assessments for obtaining a license or quality label, but they are actually there for the benefit of patients and staff. Even without an accreditation or certification label, each clinic should start by looking critically at their clinical practice with the goal to improve clinical care and clinical outcomes. Since most of the papers on indicators in ART focusses on the laboratory aspect, this paper wanted to give clinics a minimal list of indicators to start monitoring their clinical performance. Although challenging and maybe not ambitious enough according to the commentator, we do hope that centres will jump the wagon concerning clinical PIs leading to improvements in clinical practice in ART.

## Conflict of interest

None.

## References

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