

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

Sir,

We read with great interest the paper 'The Maribor consensus: report of an expert meeting on the development of performance indicators for clinical practice in ART' (Vlaisavljevic *et al.*, 2021). This paper reported the results of a vast undertaking to define a set of performance indicators (PIs) for clinical work in ART. From these efforts, six PIs to be used for monitoring clinical work in ovarian stimulation for ART, embryo transfer and pregnancy achievement have been recommended: cycle cancellation rate, rate of cycles with moderate/severe ovarian hyperstimulation syndrome, the proportion of mature oocytes (metaphase II) at ICSI, complication rate after oocyte retrieval, clinical pregnancy rate and multiple pregnancy rate. However, in our opinion, this interesting paper appears to be affected by several flaws that may frustrate the authors' intent.

First, in our opinion, the final goal of ART should clearly be the birth of a healthy baby for couples who struggle for that. The most relevant PI should be the live birth rate, since a live born is the purpose of patients as well as physicians and embryologists working in ART clinics. Furthermore, European countries suffer alarming denatality associated with a rise in the age of women seeking childbearing; consequently, the aim of all clinics should be to provide the best chance to infertile patients to have children. Live birth rate is a better PI than clinical pregnancy rate; indeed, the annual reports of ART in USA SART/CDC (CDC-Assisted Reproductive Technology (ART)-National ART Surveillance, 2020) and UK Authority (HFEA, 2019) show data in terms of live birth rate. This may increase the burden for ART clinics to collect data but is a more accurate indicator of performance.

Women's age is the most relevant predictor of outcome in ART: this is well-known and recognized worldwide. Moreover, the age of women undergoing ART is constantly and continuously growing, such as shown from the data presented in the CDC/SART annual report (CDC-Assisted Reproductive Technology (ART)-National ART Surveillance, 2020), the UK Authority report (HFEA, 2019) and ESHRE data (Wyns *et al.*, 2021). These reports showed that more than 30% of all patients are  $\geq 40$  years of age, and to rule out these patients from PI evaluation, as suggested in this paper, seems unfair and uncorrected. To exclude more than one-third of all cases from the evaluation of performance rating will result in incorrect evaluations on the performance of ART clinics. Indeed, the performance of ART clinics with low patient inflow (100–200 cases per year), for instance, may be under-estimated depending on the number of couples aged  $\leq 39$  years old observed in their activity. In addition, in clinics with higher patient inflow, the exclusion of more than one-third of patients with worse reproductive outcomes may overestimate the clinics' performance. To exclude women  $\geq 40$  years old from PI evaluation might have made sense years ago when the ESHRE Guidelines on Good

Practice in IVF Lab (ESHRE Special Interest Group of Embryology and Alpha Scientists in Reproductive Medicine, 2017) were elaborated, but today it is misleading, considering the high numbers of these patients. Consequently, we should bring the PI estimation back to the 'real world'. All patients should be included in the IP rating due to the continuing increase in the age of women undergoing IVF. Perhaps the IVF outcome data for each age group of women should be corrected using an algorithm that takes into account the number of cases and the expected success rate for each age group to obtain a more equilibrated evaluation of the outcomes?

Furthermore, we would like to highlight the absence of blastocyst transfer and single embryo transfer rates from the PIs chosen from the Maribor consensus. These are in the policies of many ART clinics and are supported by the National Health Systems of several European countries. These indexes, e.g. those reported in the Vienna Consensus on the ART laboratory PIs (ESHRE Special Interest Group of Embryology and Alpha Scientists in Reproductive Medicine, 2017), should be included in the PIs as they are benchmarks of good clinical practice in ART clinics.

Monitoring the quality of the services offered to patients by ART clinics will play a fundamental role in the future, and reliable and validated PIs are required to do this. Furthermore, the quality assessment of ART clinics may be used by social health systems or private insurance companies to evaluate the competency of each ART clinics and, consequently, which clinics will be affiliated to a particular National Health System or whose patients will be eligible for reimbursement for IVF cycle costs from their health insurance policies.

The development of reliable and updated PIs is urgent and, despite the commitment of the participants to the Maribor consensus conference, it is time for a general rethinking and reappraisal of PIs in IVF, which must be more adherent to the 'real world'.


## Conflict of interest


None.

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