Review

The Vienna consensus: report of an expert meeting on the development of ART laboratory performance indicators

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KEY MESSAGE

This proceedings report presents 19 Indicators, including 12 Key Performance Indicators (KPIs), 5 Performance Indicators (PIs), and 2 Reference Indicators (RIs) from an international workshop supported by the European Society of Human Reproduction and Embryology (ESHRE) and Alpha Scientists in Reproduction (Alpha), designed to establish consensus on definitions and recommended values for the assisted reproductive technology (ART) laboratory.

A B S T R A C T

This proceedings report presents the outcomes from an international workshop supported by the European Society of Human Reproduction and Embryology (ESHRE) and Alpha Scientists in Reproductive Medicine, designed to establish consensus on definitions and recommended values for Indicators for the assisted reproductive technology (ART) laboratory. Minimum performance-level values ('competency') and aspirational ('benchmark') values were recommended for a total of 19 Indicators, including 12 Key Performance Indicators (KPIs), five Performance Indicators (PIs), and two Reference Indicators (RIs).

Introduction

Performance Indicators (PIs) are objective measures for evaluating critical healthcare domains (patient safety, effectiveness, equity, patient-centeredness, timeliness and efficiency) (Kohn et al., 2000). In the setting of a clinical laboratory, quality indicators are necessary for systematically monitoring and evaluating the laboratory's contribution to patient care (ISO-15189:2012) and they represent an important element within the quality management system (QMS) (ESHRE Guideline Group on Good Practice in IVF Labs et al, 2016; Mortimer and Mortimer, 2015). Currently, there are no established PIs for assisted reproductive technology (ART) laboratories, and there is very little published evidence on the topic.

Any PI should be reliable and robust, and routine data collection for the indicator should be straightforward. Furthermore, the biological or technical process to be monitored should be defined, and relevant qualifiers, confounders and endpoints should be identified. Key Performance Indicators (KPIs) are Indicators deemed essential for evaluating the introduction of a technique or process; establishing minimum standards for proficiency; monitoring ongoing performance within a QMS (for internal quality control (IQC), external quality assurance (EQA)); benchmarking and quality improvement. In general, the results of a series of KPIs will provide an adequate overview of the most important steps in the IVF laboratory process (Salinas et al., 2010).

The aim of the consensus meeting and report was to establish KPIs for ART laboratories for use in monitoring 'fresh' IVF and ICSI cycles and provide the basis for several of the quantitative performance criteria needed to create competency profiles for clinical embryologists. More specifically, the purpose was to achieve an international consensus regarding: (i) a minimum list of IVF laboratory indicators and KPIs that in the future can be further extended and/or revised; (ii) specific definitions for these indicators (including necessary case inclusion/exclusion criteria; and calculation formulae); and (iii) recommended values for each KPI (minimum 'competency' limit; and 'aspirational goal' benchmark).

Based on the information presented here, each laboratory should develop its own set of KPIs founded on laboratory organization and processes, and develop a systematic, transparent, and consistent approach to data collection and analysis and calculation of KPIs (ESHRE Guideline Group on Good Practice in IVF Labs et al, 2016; Mayer et al., 2003; Mortimer and Mortimer, 2015; Salinas et al., 2010).

Table 1 – Consensus workshop participants and contributors.	
Participant/contributor name	**Affiliation**
Susanna Apter	Fertilitetscentrum Stockholm, Sweden
Basak Balaban	American Hospital of Istanbul, Turkey
Alison Campbell[a]	CARE Fertility Group, UK
Jim Catt	Optimal IVF, Melbourne, Australia
Giovanni Coticchio	Biogenesi, Monza, Italy
Maria José de los Santos[a]	IVI Valencia, Valencia, Spain
Sophie Debrock[a]	Leuven University Fertility Centre, Leuven, Belgium
Thomas Ebner[a]	Kepler University, Linz, Austria
Stephen Harbottle	Cambridge IVF, UK
Ciara Hughes	Rotunda IVF, Dublin, Ireland
Ronny Janssens	Centre for Reproductive Medicine, Brussels, Belgium
Nathalie Le Clef	ESHRE Central Office, Grimbergen, Belgium
Kersti Lundin	Sahlgrenska University Hospital, Sweden
Cristina Magli[a]	SISMER, Bologna, Italy
David Mortimer[a]	Oozoa Biomedical, Vancouver, Canada
Sharon Mortimer	Oozoa Biomedical, Vancouver, Canada
Zsolt Peter Nagy	Reproductive Biology Associates, Atlanta, USA
Johan Smitz[a]	Centre for Reproductive Medicine, Brussels, Belgium
Arne Sunde	St Olav's University Hospital, Trondheim, Norway
Nathalie Vermeulen	ESHRE Central Office, Grimbergen, Belgium
[a] Presenter at the consensus workshop.	

Methodology

This report is the result of a 2-day consensus meeting of expert professionals (participants are listed in **Table 1**). As a starting point for the discussion at the meeting, two surveys were organized to collect information on indicators used in IVF laboratories. The first, the 'Alpha survey', was sent to national and international societies of ART laboratory directors and clinical embryologists, and to the members of the European Society of Human Reproduction and Embryology (ESHRE) committee of national representatives. Eighteen responses were received out of 34 sent, with opinions from Australia, Austria, Belgium, Bulgaria, Canada, Croatia, France, Germany, Ireland, Italy, Japan, Slovenia, Sweden, South Africa, Turkey, UK, and USA, and the results of this survey informed the expert panel on minimum expected, or competence, values (i.e. values that any laboratory should be able to achieve), and aspirational, or benchmark, values (i.e. values that can be employed as a best practice goal), for a range of quality indicators. Where possible, responses were based on standardized information (national collected data, or large datasets), but in most countries such data are not available. Another survey, the 'ESHRE survey', provided information on current practice (How many KPIs are measured, frequency of measurement, characteristics of a reference population for KPIs) and the degree of importance of some indicators. This survey was sent to 2413 members of the ESHRE Special Interest Group (SIG) of Embryology, and 384 responses were received. In addition, where relevant, published data were collected from a literature search and summarized, although for most indicators,

especially in ART, there is a general lack of evidence to support their importance, scientific soundness and usefulness (Shahangian and Snyder, 2009).

During the consensus meeting, the results of the surveys, scientific evidence and personal clinical experience were integrated into presentations by experts on specific topics. For each indicator, information was presented in a fixed format: definition, rationale, qualifiers, formula, data sources, KPI strengths and weaknesses, frequency of data collection and reference values for minimum expected and target values based on 50 and 75 percentile values, respectively. After the presentation for the topic, each proposed indicator was discussed until consensus was reached within the group.

After the meeting, a report was prepared describing the presentations (workshop report) and the consensus points. After approval of the report by the meeting participants, the national and international societies that contributed to the questionnaires were invited to review the report and submit comments. The final version of the manuscript was approved by the Executive Committees of ESHRE and Alpha before publication.

This paper is divided into two parts: the workshop report, and the recommendations of the Expert Panel.

Workshop report

Effects of ovarian stimulation on embryology parameters

The methods of ovarian stimulation have been evolving since the earliest days of clinical IVF, in the search for the best stimulation protocol. With that goal in mind, there has been an enormous effort to develop