THE VIENNA CONSENSUS: REPORT OF AN EXPERT MEETING ON THE DEVELOPMENT OF ART LABORATORY PERFORMANCE INDICATORS

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VUB

DISCLOSURE

I declare that no commercial or financial interest has influenced the content of this presentation

INHOUD

Part I KPI

Part II Benchmarking

Part III The Vienna consensus

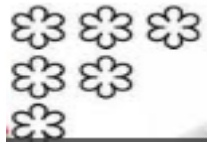
INTRODUCTION

1900 France

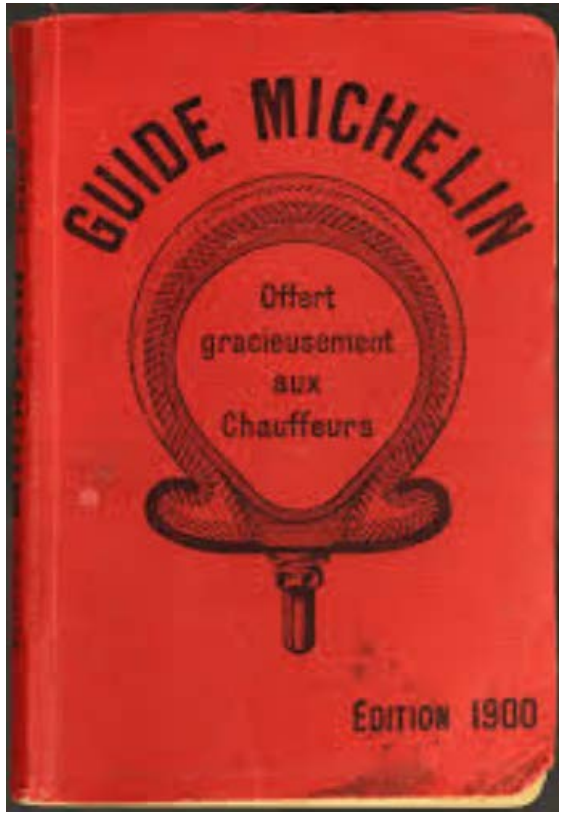
- <3000 cars

1911 UK

1926



1961 Mc Kinsey & Company



Motorists will be
Overlooking a Good Thing
if they neglect to obtain a copy of the
Michelin Guide to the British Isles.
Everything you want to know about anywhere you want to go is fully set out in this handy volume

Little John Day
Had lost his way
And didn't know how to find it;
Now he takes on his ride
A new Michelin Guide,
And, like me, he is always behind it.

NOTE.—In view of the enormous number of recent libel actions, I hereby do solemnly declare that the said "JOHN DAY" is as unknown to me as "LITTLE BO-PEEP."

The British Guide can be obtained from the Michelin Touring Office on receipt of 6d. in stamps to cover postage, packing, etc., or a copy can be procured from any Michelin Stockist.

MICHELIN TYRE CO., LTD.,
81, FULHAM ROAD, CHELSEA, LONDON, S.W.

Telephone: 4400 Kensington (6 lines).
Telegrams: "Pneumatic," or "Bibendum," London.

STANDARDS AND INDICATORS

ISO 9001:2015

ISO 15189 ACCREDITATION
MEDICAL LABORATORY

NEN EN 15224 | Eisen gebaseerd op EN-ISO 9001

ISO 15189 - 4.14.7 Quality indicators

- The laboratory shall establish quality indicators to monitor and evaluate performance throughout critical aspects of pre-examination, examination and post-examination processes.

CHARACTERISTICS OF A GOOD KPI

Important and relevant

Vital for the activity

Drives improvement - target

Reliable, useful, accurate

- Clear objectives
- Up to date - dynamic
- Effective: simple and easy to understand
- Accurate: does it assess what I am interested in?

Robust: minimize confounders

Owned: Responsibilities defined

Easy to generate - IT

KPI SUMMARY TABLE

Name of indicator

Definition: description of what is measured

Rationale, Purpose: for what, to be used by who

Formula, Numerator, denominator: specific, inclusion, exclusion criteria

Qualifiers: reference group

Strenghts, weaknesses

Type of indicator: process, financial…

Target : competency and benchmark values

Data sources: reference values

Frequency, period, case load

Communication: frequency, method, target audience

Responsables: indicator, data collection, analysis

KPI IN IVF: LITERATURE

Total quality improvement in the IVF laboratory: choosing indicators of quality. Mayer et al. Reprod Biomed Online, 2003

Defining poor and optimum performance in an IVF programme. Castilla et al. Hum Rep 2008

Quality indicators for all dimensions of infertility care quality: consensus between professionals and patients. Dancet et al. Hum Rep 2013

Developments in IVF warrant the adoption of new performance indicators for ART clinics, but do not justify the abandonment of patiënt-centred measures. Wilkinson et al. Hum Rep 2017

ESHRE revised guidelines for good practice in IVF laboratories (2015)

2.4 All relevant data concerning laboratory work must be recorded in a database that allows KPI extraction and statistical analysis.

2.9 KPIs should be objective and relevant, regularly checked and discussed, and communicated to all staff. KPIs can be based on a reference patient group with good prognosis, as well as on the whole patient population. Appropriate statistics can be used to account for patient variation and the number of previous treatment cycles patients may have already undertaken.

2.10 Critical performance levels should be defined for each KPI with reference to national data and European registry data collected by the European IVF-monitoring programme for ESHRE. If necessary, appropriate action should be taken.

2.11 In addition to laboratory and clinical performance, operator performance should be checked regularly to ensure competence, compliance and consistency, via direct observation of procedural skills (DOPS) and/or individual KPIs. If necessary, retraining should be implemented.

“A group of expert is currently working on an overview of Key Performance Indicators (KPIs) for ART labs and their definition.”

KPI ON DIFFERENT LEVELS

Generic

- Growth
- Lost patients, new patients
- Client satisfaction

Financial

- Rentability
- Costs/turnover

Human Resources

- Turn over
- Training
- Employee satisfaction

Process

MEASURING QUALITY: PERFORMANCE INDICATORS

Embryology

- Oocyte maturity
- Fertilisation rate
- Cleavage rate
- …

QMS

- Incident reports
- Complications
- Equipment failures
- Complaints
- ….

Staff performance

- ICSI
- Vitrification
- Embryoreplacement
- Biopsy

Outcome

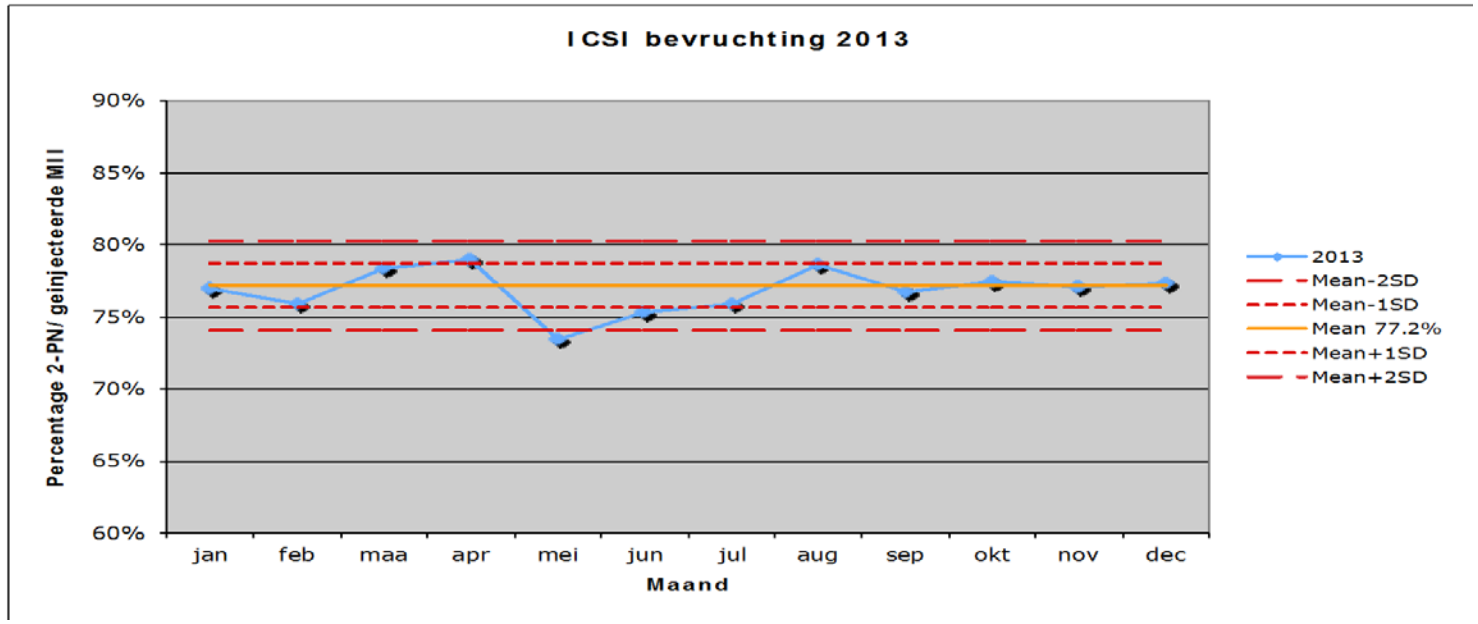
- +hCG
- Implantation
- Pregnancy rates
- Multiple pregnancies
- …

LEVEY-JENNINGS CONTROL CHART

Frequency: based on case load – monthly - min 30 cycles

QC data on Shewart chart

Westgard rules



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ACT!

Monthly

Action (PDCA)

Documented

Follow-up

Review targets: management review

INHOUD

Part I KPI

Part II Benchmarking

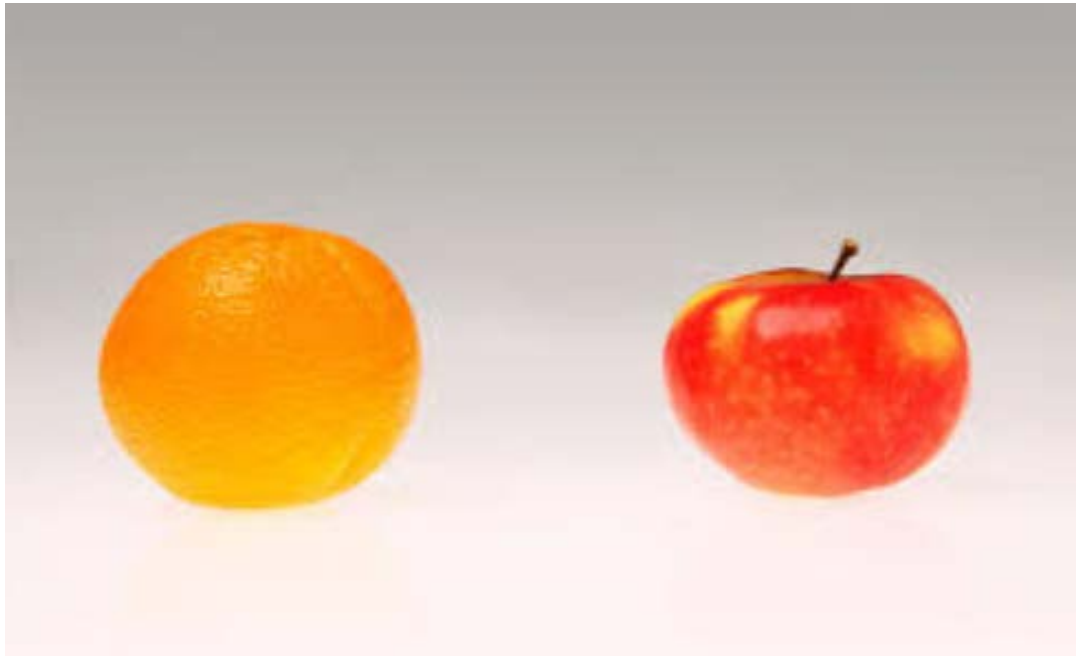
Part III The Vienna consensus

BENCHMARKING: DEFINITION

The process of comparing one's business processes and performance metrics to industry bests and best practices from other companies.

(Wikepedia)

BENCHMARKING



BENCHMARKING PITFALLS

1. Compare apples and oranges
2. Vague objective
   - What are you intersted in learning?
   - What do you want to achieve?
3. Lack of ambition
   - Compare to average
   - Select bad peer group
4. Lack of action/communication

NATIONAL REGISTER: EXAMPLE BELGIAN REGISTER (BELRAP) 2013

Clinics can compare to others

Aspirational goal?

Average pulled down

Rest of the world?

BELGIAN REGISTER (BELRAP) 2013

Belrap 2013

Table 2.29 Own fresh cycles: Number of HCG+ pregnancies according to age and rank

Rank	1	2	3-6	>=7	Total
< 36 (yrs)					
All Centres (N=10147, Missing=528)					
Aspirations	4257	2480	3222	188	10147
Transfers	3772	2207	2905	159	9043
HCG + per aspiration cycle	1583/4251 (37.2%) (37.2% - 37.3%)	920/2474 (37.2%) (37.1% - 37.3%)	1231/3216 (38.3%) (38.2% - 38.4%)	58/182 (31.9%) (30.9% - 34.0%)	3792/10123 (37.5%) (37.4% - 37.6%)
HCG + per embryo transfer	1583/3766 (42.0%) (42.0% - 42.1%)	920/2202 (41.8%) (41.7% - 41.9%)	1231/2899 (42.5%) (42.4% - 42.6%)	58/156 (37.2%) (36.5% - 38.4%)	3792/9023 (42.0%) (41.9% - 42.2%)

NA=no cycles with data available.
In the calculation of the ratios, only cycles with available data are considered. In the line underneath, the range expresses the minimum and maximum possible rates when accounting for missing data by considering missing HCG results as negative and positive, respectively.

CRG 2013

table 2.24	rank 1	rank 2	rank 3-6	rank ≥7	Total
Aspirations	858	477	812	102	2249
Transfers	741	386	689	84	1900
hCG+	395	205	353	40	993
hCG per aspiration (%)	46,04	42,98	43,47	39,22	44,15
hCG per ET (%)	53,31	53,11	51,23	47,62	52,26

Belrap - CRG

table 2.29	rank 1	rank 2	rank 3-6	rank ≥7	Total
Aspirations	3399	2003	2410	86	7898
Transfers	3031	1821	2216	75	7143
hCG+	1188	715	878	18	2799
hCG per aspiration (%)	34.9	35.7	36.4	20.1	35.4
hCG per ET (%)	39.2	39.3	39.6	24.0	39.2

INHOUD

Part I KPI

Part II Benchmarking

Part III The Vienna consensus

The Vienna Consensus on KPIs and benchmarks for IVF/ICSI

Sharon Mortimer

Alpha Board Member

Vancouver, Canada

Background

- Performance Indicators (PIs) provide objective measures of healthcare domains, such as patient safety, equity, quality of service, etc.
- In the ART laboratory, PIs support systematic monitoring and evaluation of the laboratory's contribution to patient care
- PIs are an important component in the quality management system of the lab, and of the clinic
- Consensus KPIs for cryo cycles were published by Alpha in 2012.
- There were no established PIs for fresh IVF/ICSI cycles, and very little evidence in the literature to suggest generally useful values

Aim

- The general aim of this project was to establish KPIs for ART laboratories to monitor fresh IVF and ICSI cycles.
- The specific purpose was to achieve an international consensus regarding:
  - A minimum list of ART laboratory indicators that could be later extended and/or revised
  - Specific definitions for these indicators (including specific inclusion/exclusion criteria and calculation formulas)
  - Recommended values for each KPI: minimum value (for the definition of “competency”) and “aspirational goal” benchmark value.

Approach

- 2-day consensus meeting of expert professionals, co-hosted by ESHRE Special Interest Group Embryology and ALPHA Scientists in Reproductive Medicine
- Held in Vienna, September 2016.
- Before the meeting, two surveys were administered:
  1. The Alpha survey
  2. The ESHRE survey

Approach: ALPHA survey

- Survey of the minimum expected value and benchmark value for a range of indicators
- Sent to national and international societies of ART laboratory directors and Clinical Embryologists and to members of the ESHRE committee of national representatives
- 18 responses / 34 sent
- Where possible, responses referenced national collected data or large datasets (i.e. standardized information)

Approach: ESHRE survey

- Survey of current practice:
  - How many KPIs measured
  - Frequency of measurement
  - Reference population characteristics
- Also surveyed the degree of importance of some Indicators
- Sent to members of ESHRE SIG Embryology
- 384 responses / 2413 sent
- Where possible, responses referenced national collected data or large datasets (i.e. standardized information)

Consensus Meeting Participants

- Susanna Apter, Sweden
- Basak Balaban, Turkey
- Alison Campbell*, UK
- Jim Catt Optimal IVF, Australia
- Giovanni Coticchio, Italy
- Sophie Debrock*, Belgium
- Maria José de los Santos*, Spain
- Thomas Ebner*, Austria
- Stephen Harbottle, UK
- Ciara Hughes, Ireland
- Ronny Janssens, Belgium
- Nathalie Le Clef, Belgium
- Kersti Lundin, Sweden
- Cristina Magli*, Italy
- David Mortimer*, Canada
- Sharon Mortimer, Canada
- Zsolt Peter Nagy, USA
- Johan Smitz*, Belgium
- Arne Sunde, Norway
- Nathalie Vermeulen, Belgium

* presenter

Approach: Consensus Meeting

- Any published data were summarized, but usually this did not yield useful information for the purposes of the consensus.
- Presentations included results of the surveys, scientific evidence, and personal clinical experience.
- For each potential Indicator, information was presented as:
  - Definition
  - Rationale
  - Qualifiers
  - Formula
  - Data sources
  - Strengths and weaknesses
  - Frequency of data collection
- Reference values for minimum expected and target values for each Indicator were based on 50th and 75th percentile values, respectively.
- Each proposed Indicator was discussed until consensus was reached.

Outcome of discussions

The consensus committee agreed on a total of 19 Indicators, split into three groups:

- **Reference Indicators (RIs)** = related to the quality of the oocytes coming into the lab, so proxy indicators of quality
- **Performance Indicators (PIs)** = data should be documented and stored, not necessarily on a control chart
- **Key Performance Indicators (KPIs)** = related to the “core business” of the ART laboratory

For each Indicator, as appropriate, there were “competency” values and aspirational “benchmark” values.

Vienna Consensus: Reference Indicators

Reference Indicator	Calculation	Benchmark Value
Proportion of oocytes recovered (stimulated cycles)	$\frac{\text{no. oocytes retrieved} \times 100}{\text{no. follicles on day of trigger}}$	80 – 95% of follicles measured
Proportion of MII oocytes at ICSI	$\frac{\text{no. MII oocytes at ICSI} \times 100}{\text{no. COCs retrieved}}$	75 – 90%

COC = cumulus-oocyte complexes; MII = metaphase II

Vienna Consensus: Performance Indicators

Performance Indicator	Calculation	Competency Value	Benchmark Value
Sperm motility post-preparation (for IVF and IUI)	$\frac{\text{Progressively motile sperm} \times 100}{\text{All sperm counted}}$	90%	≥ 95%
IVF polyspermy rate	$\frac{\text{No. fertilized oocytes with >2PN} \times 100}{\text{No. COCs inseminated}}$	< 6%	
1PN rate (IVF)	$\frac{\text{No. 1PN oocytes} \times 100}{\text{No COCs inseminated}}$	< 5%	
1 PN rate (ICSI)	$\frac{\text{No. 1PN oocytes} \times 100}{\text{No. MII oocytes injected}}$	< 3%	
Good blastocyst development rate	$\frac{\text{No. good quality blastocysts on day 5} \times 100}{\text{No. 2PN/2PB oocytes on day 1}}$	≥ 30%	≥ 40%

Vienna Consensus: Key Performance Indicators (1)

Key Performance Indicator	Calculation	Competency Value	Benchmark Value
ICSI damage rate	$\frac{\text{No. damaged or degenerated} \times 100}{\text{All oocytes injected}}$	≤ 10%	≤ 5%
ICSI normal fertilization rate	$\frac{\text{No. 2PN/2PB oocytes} \times 100}{\text{No. MII oocytes injected}}$	≥ 65%	≥ 80%
IVF normal fertilization rate	$\frac{\text{No. 2PN/2PB oocytes} \times 100}{\text{No COCs inseminated}}$	≥ 60%	≥ 75%
Failed fertilization rate (IVF)	$\frac{\text{No. cycles with no evidence of fertilization} \times 100}{\text{No. stimulated IVF cycles}}$	< 5%	

Vienna Consensus: Key Performance Indicators (2)

Key Performance Indicator	Calculation	Competency Value	Benchmark Value
Cleavage rate	$\frac{\text{No. cleaved embryos on day 2} \times 100}{\text{No. 2PN/2B oocytes on day 1}}$	≥ 95%	≥ 99%
Day 2 embryo development rate	$\frac{\text{No. 4-cell embryos on day 2} \times 100}{\text{No. 2PN/2B oocytes on day 1}}$	≥ 50%	≥ 80%
Day 3 embryo development rate	$\frac{\text{No. 8-cell embryos on day 3} \times 100}{\text{No. 2PN/2B oocytes on day 1}}$	≥ 45%	≥ 70%
Blastocyst development rate	$\frac{\text{No. blastocysts on day 5} \times 100}{\text{No. 2PN/2B oocytes on day 1}}$	≥ 40%	≥ 60%

Vienna Consensus: Key Performance Indicators (3)

Key Performance Indicator	Calculation	Competency Value	Benchmark Value
Successful biopsy rate	$\frac{\text{No. biopsies with DNA detected} \times 100}{\text{No. biopsies performed}}$	≥ 90%	≥ 95%
Blastocyst cryosurvival rate	$\frac{\text{No. blastocysts appearing intact} \times 100}{\text{No. blastocysts warmed}}$	≥ 90%	≥ 99%
Implantation rate (cleavage stage)	$\frac{\text{No. sacs seen on US} \times 100}{\text{No. embryos transferred}}$	≥ 25%	≥ 35%
Implantation rate (blastocyst stage)	$\frac{\text{No. sacs seen on US} \times 100}{\text{No. blastocysts transferred}}$	≥ 35%	≥ 60%

Cryopreservation KPIs

- Apart from the updated KPI for blastocyst cryosurvival, which reflects the worldwide trend towards vitrification since 2011, all other KPIs from the Alpha Cryo Consensus are still current.

Reproductive BioMedicine Online (2012) **25**, 146–167

ELSEVIER

www.sciencedirect.com
www.rbmonline.com

ARTICLE

The Alpha consensus meeting on cryopreservation key performance indicators and benchmarks: proceedings of an expert meeting

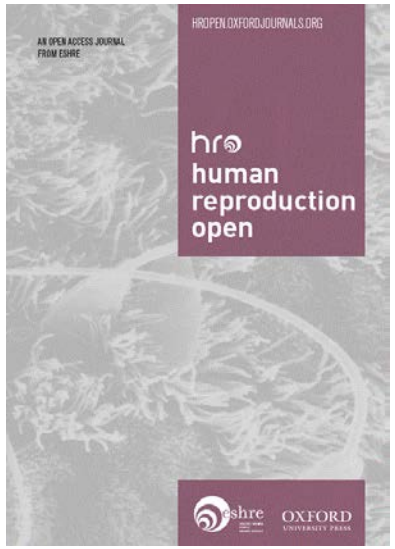
Alpha Scientists in Reproductive Medicine [1,*]

Implantation Rates

- The decision to follow Implantation Rates was simply as a marker of laboratory performance
- Therefore, this is not the same as the use of this metric for the purpose of comparing results of clinical trials, which is currently under some discussion
- The definition for Implantation Rate in the Vienna Consensus uses fetal sacs (rather than fetal hearts) in its calculation – this was a consensus decision reached after some discussion, to conform to international registries

Fresh IVF / ICSI KPIs Consensus

Simultaneous publication in *Human Reproduction Open* and *Reproductive Biomedicine Online*



***Human Reproduction Open*, Volume 2017, Issue 2, 12 July 2017, hox011, https://doi.org/10.1093/hropen/hox011**

RBM ONLINE

Reprod Biomed Online 35:494-510, 2017

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Review

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

CrossMark

ESHRE Special Interest Group of Embryology and Alpha Scientists in Reproductive Medicine [a,b,*]

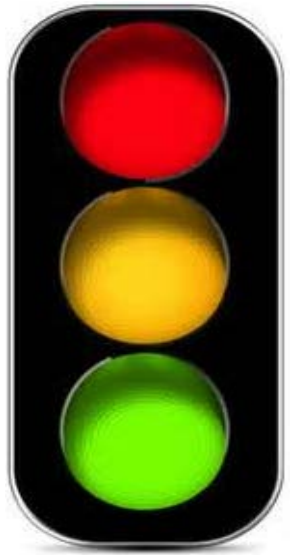
Support for the Consensus Meeting

- Financial support for the Vienna Consensus meeting was provided by ESHRE and Alpha Scientists in Reproductive Medicine
- Alpha gratefully acknowledges the receipt of unrestricted educational grants from the Global Fertility Alliance, Merck KGaA, Origio, and Vitrolife
- The following societies provided valuable insights on the laboratory performance indicators: BLEFCO (France), AGRBM (Germany), ICE (Ireland), SIERR (Italy), SASREG (South Africa), KED (Turkey), and ACE (UK)
- The respondents to the questionnaires are thanked for their valuable contribution to the Vienna Consensus

ANNUAL REVISION OF KPIS

Management review

Indicator	ESHRE/Alpha		UZ
			2016
	Competency	**Benchmark**	
Sperm motility post-preparation (for IVF and IUI)	90%	≥ 95%	
IVF polyspermy rate	< 6%		
1 PN rate (IVF)	< 5%		<5%
1 PN rate (ICSI)	< 3%		<3%
ICSI damage rate	≤ 10%	≤ 5%	<7%
ICSI normal fertilization rate	≥ 65%	≥ 80%	≥ 75%
IVF normal fertilization rate	≥ 60%	≥ 75%	≥ 55%
Failed fertilization rate (IVF)	< 5%		<5%
Day 3 Embryo development rate*	≥	≥	≥ 60%
Blastocyst development rate	≥ 40%	≥ 60%	≥ 40%
Oocyte cryosuvival rate	/	/	≥ 75%
Embryo cryosurvival rate	/	/	≥ 90%
Blastocyst cryosurvival rate	≥ 90%	≥ 99%	≥ 90%



THANK YOU

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