



# Key indicators of quality in PGD

Katerina Vesela, M.D., Ph.D.  
REPROMEDA Brno,  
Centre for Reproductive Medicine and Preimplantation Diagnosis  
[kvesela@repromeda.cz](mailto:kvesela@repromeda.cz)

# Continual improvement

- Continual improvement is both a formal requirement and a natural outcome of ISO 15189, based on regular audit and review of procedures, training for personnel and users, CAPA (corrective actions/preventive actions), etc.
- The system must be regularly and continuously evaluated to identify problems and areas for improvement
- The quality improvement cycle was described by Dr. W. Edwards Deming.
- This cycle for quality assurance consists of four steps: *Plan, Do, Check, and Act*. (PDCA cycle).

# Continual improvement and quality indicators

- ISO 15189 (section 4.12.4) requires the Laboratory management shall implement *quality indicators* for systematically monitoring and evaluating
- *Quality indicators* should be developed to cover as much lab activities as possible in both aspects – technical and management

# Quality indicators

- **Specific**
- **Measurable**
- **Achievable**
- **Relevant**
- **Time-bound**

# Quality indicators

- For each quality indicator it is supposed to be measured and documented
  - how often it is going to be measured
  - what are the limits
  - what happens if the limits are not met
- Quality indicators are analysed and presented at the Annual Management Review (ISO 15189 section 4.15)

# Client-provider relationship and communication in PGD program

- Patient – focused approach is a paramount principle in a good clinical practise
- Furthermore it is not the only relationship of importance
- PGD is multidisciplinary and more types of client-provider relationship exists
- Customers are both patients and clinicians
- Clear lines of communication (face-to-face, email, teleconferencing)

# Quality indicators for PGD - Technical (Examples)

- Number of new tests deployed
- Number of patients/PGD cases
- Positive result rate/pregnancy rate
- TAT (turnaround time from patients specimen reception to preparatory work-up being completed)
- EQA results

# Quality indicators for PGD - Technical (Examples)

- IQC (internal quality control) results
- Test failures/contamination
- Number/level of misdiagnosis
- Confirmation of results in untransferred embryos
- Misdiagnosis per untransferred embryo



# Quality indicators for PGD – Management (Examples)

- Complaints and compliments
- Complaint response time
- Customer satisfaction survey
- Meetings with IVF unit
- Analytical nonconformities

# Quality indicators for PGD – Management (Examples)

- Outcomes of internal/external audits
- Documents revised a created
- Corrective action completion
- Maintenance of staffing levels
- Maintenance of accreditation

# Key aspects of quality

- Orientation towards customer/patient/clinician
- Constant efforts for improvement
- „Zero-mistake“ principle (preventing and forestalling mistakes before they happen)
  - Costs of forestalling mistakes are much lower than the costs of repairing them afterward
- Flattening the hierarchy through collective responsibility of all employees
- Quality structure becomes a firm part of the management of employees

# Quality is what is right.

Theodor Heus, 1962