

Quality Control in the ART Unit

Peter Kastrop, Ph.D.
Clinical embryologist



Kiev, Ukraine, 26-27 May 2010

Quality



Invisible when **GOOD**

Impossible to ignore when **BAD**

Kiev, Ukraine, 26-27 May 2010

Quality



The total sum of properties and characteristics of a product, process, or service which is vital in order to meet the requirements as determined or assumed needs

ISO definition



expectation / trust / satisfaction

Kiev, Ukraine, 26-27 May 2010

Quality in the ART unit



- level of patients care
- success rates
-



Kiev, Ukraine, 26 -27 May 2010

Quality in the ART unit

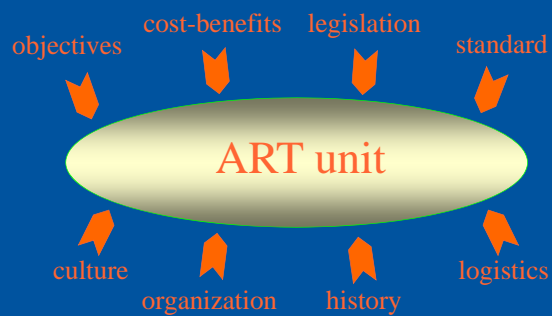


- measurable
- manageable
- product / service
- end product / endpoint
- expectations of the patients



Kiev, Ukraine, 26 -27 May 2010

Quality management



Kiev, Ukraine, 26 -27 May 2010

Quality management



Quality Standards / Quality management systems

- by professional societies
 - AFS, ACE, ESHRE Guidelines
- international standards
 - ISO 9001, ISO 17025, ISO 15189
- Quality Management Models
 - TQM, EFQM

Kiev, Ukraine, 26 -27 May 2010

Quality management



Basic concepts

Quality Control (QC):

the operational techniques and activities which are carried out in order to meet the quality requirements

Quality Assurance (QA):

the total sum of all planned and systematic activities required in order to establish sufficient trust that a product or service meets the quality requirements as determined

ISO definitions

Kiev, Ukraine, 26 -27 May 2010

Quality control (QC)



Ensuring optimal conditions

- detailed written standard procedures
- procedure, safety and policy manuals
- appropriately educated and trained personnel
- correct operation and calibration of instruments
- consistent and proper execution of appropriate techniques and methods
- documentation and record keeping
- system for patient sample collection and management
- system for the appraisal of performance and correction of deficiencies

Kiev, Ukraine, 26 -27 May 2010

Quality Assurance (QA)



Surveillance of optimal conditions

- system for unambiguous patient and patient sample identification
- ongoing method of assessing staff competency in terms of their clinical and clerical skills
- monitoring and evaluation of number and type of accidents, mistakes and deviations
- system for addressing and documenting complaints
- system for the implementation of advances and improvements
- application of apparent outcome indicators or laboratory performance measures

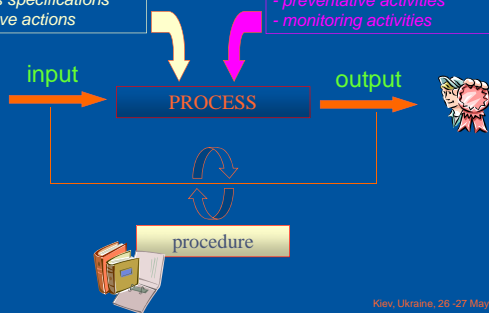
Kiev, Ukraine, 26 -27 May 2010

Quality management



Quality Control (QC):
- process specifications
- corrective actions

Quality Assurance (QA):
- preventative activities
- monitoring activities



Kiev, Ukraine, 26 -27 May 2010

QC in the ART unit



Elements of QC in detail:

- Environment
 - Documentation
 - Personnel
 - Equipment and supplies
 - Problem management
 - Performance indicators
 - ...
- Standardization
Reproducibility
Optimization
Efficiency
Reliability

Kiev, Ukraine, 26 -27 May 2010

QC in the ART unit



Environment:

- *Appropriate location*
- *Adequate space for all activities*
- *Efficient and ergonomic design*
- *Controlled air quality*
- *Cleaning and maintenance procedures*
- *Safety and security*



Kiev, Ukraine, 26-27 May 2010

QC in the ART unit



Documentation:

paperwork / electronically

- *Quality and safety manual*
- *Detailed written standard procedures (SOPs)*
- *Working instructions*
- *Forms / records*
- *Logbooks*
- *Job description / training programs*
- *Annual reports*
- *...*



Kiev, Ukraine, 26-27 May 2010

Documentation



Quality and safety manual:

- *Quality policy and objectives*
- *Safety rules*
- *Organisation, management and personnel*
- *Facilities and accommodation*
- *Equipment and supplies*
- *Complaints and non-conformities*



Kiev, Ukraine, 26-27 May 2010

Documentation



Standard Operating Procedures (SOPs):

- Laboratory procedures
- Pre- and post laboratory procedures
- Purchase, receipt, inspection and approval
- Cleaning and maintenance
- Calibration and validation
- Audits and assessments
- Corrective and preventive actions

Kiev, Ukraine, 26 -27 May 2010

SOP

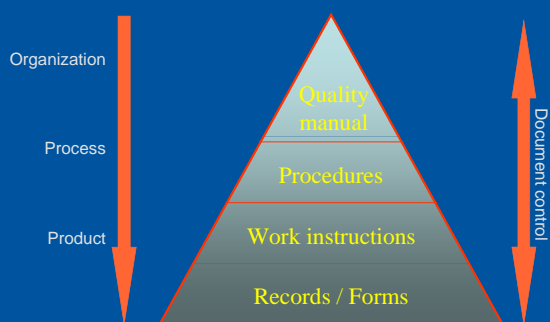


Laboratory procedure:

- Purpose and principle
- Detailed description of activities
- Facilities and requirements
- Responsibilities
- Risks / critical steps
- Safety precautions / preventive activities
- Troubleshooting
- Related documents (lab-forms)

Kiev, Ukraine, 26 -27 May 2010

Documentation



Kiev, Ukraine, 26 -27 May 2010

Document control



- *Verified and authorized*
- *Unique identification*
- *System for compilation, revision and distribution*
- *Available at relevant (work)places*
- *Document filing*



Kiev, Ukraine, 26 -27 May 2010

QC in the ART unit



Personnel:

- *Job descriptions*
 - Educational / professional qualification
 - Training and experience
 - Duties and responsibilities
- *Training and continuing education*
- *Regular competency evaluation*
 - Internal quality control (IQC) schemes
 - External quality assessment (EQA) schemes



Kiev, Ukraine, 26 -27 May 2010

QC in the ART unit



Equipment and supplies:

- *Appropriate and properly functioning equipment*
- *Regular cleaning and maintenance*
- *Calibration and validation procedures*
- *Suitable for ART (proficiency tested)*
- *Purchase and delivery schemes*
- *Receipt procedures*
- *Storage conditions*



Kiev, Ukraine, 26 -27 May 2010

QC in the ART unit



Problem management:

- Notification procedure for non-conformities
- Identification of critical steps
- Corrective and preventive measures
- Internal audits
- Management reviews



Kiev, Ukraine, 26-27 May 2010

Problem management



Critical steps:

- All actions in which samples are transferred from one dish or tube to another
- All moments where samples different origin come close to each other
- All transfers of samples to or from physicians or patients



Kiev, Ukraine, 26-27 May 2010

Problem management



- To minimise the number and severity
- To reduce the adverse impact
- To improve quality

Premise: What can we learn from it?

NOT: Who is to blame?



Kiev, Ukraine, 26-27 May 2010

QC in the ART unit



Performance indicators:

- *Operational level*
 - Equipment
 - Personnel
 - Methods (IQC and EQA schemes)
- *Outcome level*
 - Methods
 - Programme
 - Problems
- *Financial level*



Kiev, Ukraine, 26-27 May 2010

Performance indicators



Outcome level of ART programme:

Methods

- *Fertilisation rate* (ZPN, 1PN, 3PN, degen.)
- *Damage rate*
- *Cleavage rate*
- *Fragmentation rate*
- *Embryo scoring rate*
- *Embryo survival rate*
- *Sperm recovery rate*

Programme

- *Cancellation rate*
- *Implantation rate*
- *Biochemical pregnancy rate*
- *Clinical pregnancy rate*
- *Multiple rate*
- *Abortion rate*
- *Live births*

Kiev, Ukraine, 26-27 May 2010

QC in the ART unit



Additionally:

Improvement of standardization and efficiency by

- *Standardized daily schedules*
- *In advance drafted time-tables*
- *Fixed number of treatment cycles per year*
- *Even distribution during weekdays*
- *Reduced number in weekend / public holidays*

Kiev, Ukraine, 26-27 May 2010

QC in the ART unit



Daily schedule:

location	Culture unit	General laboratory	Reception / Counter	Semen laboratory
Pertains	2	2	1	1 or 2
8.00 - 9.30 h	Embryo evaluation PN inspection	Semen preparation for IUI	Receipt of samples	Semen analysis
9.30 - 12.00 h	Oocyte collection Fertilizing / Thawing	Semen preparation for IVF / ICSI	Inform patients	
12.00 - 14.00 h	Embryo selection ICSI			
14.00 - 16.00 h	Embryo transfer ICSI	Preparatory activities	Clinical activities	Semen analysis
16.00 - 16.30 h	Preparatory activities Cleaning	Cleaning		Cryopreservation patients semen
16.30 - 21.00 h				Cryopreservation donor semen

Kiev, Ukraine, 26-27 May 2010

Quality



Quality is never an accident; it is always the result of high intention, sincere effort, intelligent direction and skilful execution; it represents the wise choice of many alternatives.

William A. Foster.

Kiev, Ukraine, 26-27 May 2010
