Quality Management in the ART Laboratory – Everyone's Responsibility

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Learning Objectives

At the end of this presentation, participants should be able to:

″ Understand what quality management stands for

″ Be familiar with ISO 9001 as a quality management model for Fertility Centers

″ Appraise the importance of human resources to successful QM

What is Quality?

"characteristic, nature or essential character"
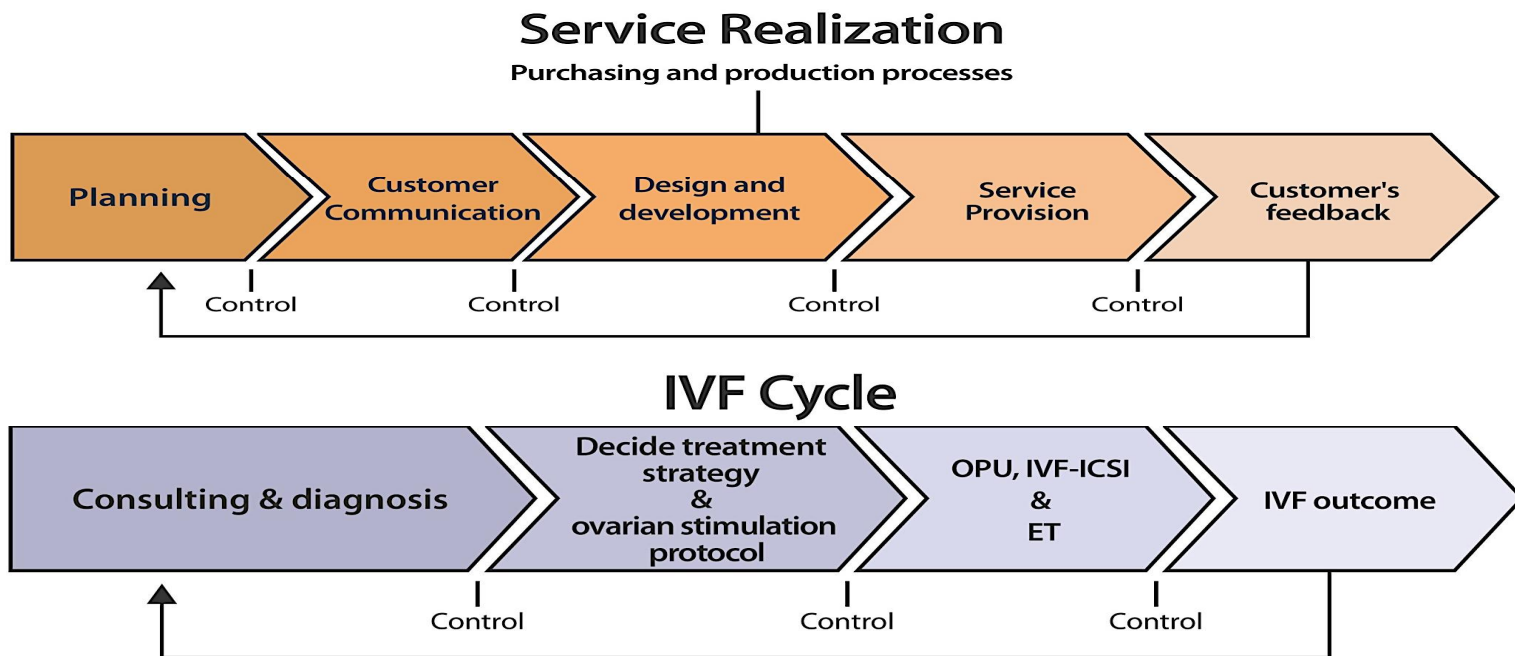
″ **Varies from person to person**

″ **Influenced by feelings**

″ **Despite being subjective in nature, it cannot be established in a vacuum**

. *Always relative to a set of requirements*

Process = Any activity or set of activities that uses resources to transform raw material, supplies and labor (inputs) into products or services (outputs)

Service Realization
Purchasing and production processes

Planning	Customer Communication	Design and development	Service Provision	Customer's feedback

Control · Control · Control · Control

IVF Cycle

Consulting & diagnosis	Decide treatment strategy & ovarian stimulation protocol	OPU, IVF-ICSI & ET	IVF outcome

Control · Control · Control

Quality in IVF is how well the outputs of our processes comply with a set of pre-defined requirements

IVF Cycle
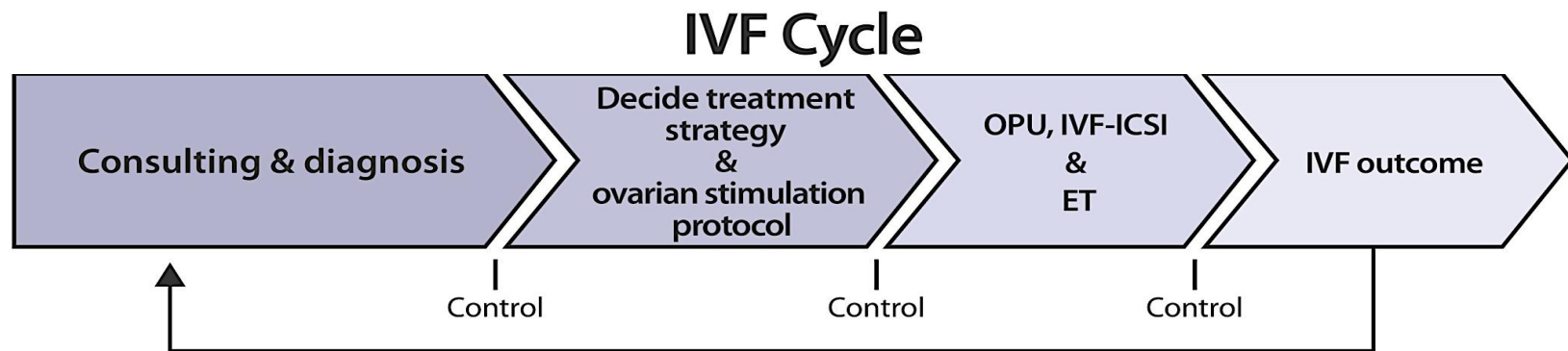
- ➢ Compliance with guidelines, regulations and expected results
- ➢ Meeting client's needs and expectations
- ➢ Continuous improvement

Doctor 'Look Good'

PR/cycle = 60%

- Established 2012
- <100 babies born
- Few credentials experience
- IVF first treatment line
- No poor responders
- Record of errors/pat. complaints
- High multiple PR
- Advertise a lot

Doctor 'Look Bad'

PR/cycle = 30%

- Established1994
- >1,000 babies born
- Lots of credentials/experience
- Manage many difficult cases
- All treatment options available
- Individualized approach
- Rare errors/patient complaints
- Low multiple PR
- Educational marketing
- Individualized patient-centered options

Improper practice patterns may lead to higher PR at the expense of good patient care

Six Most Important Quality Dimensions in Infertility Care

Effectiveness

Efficiency

Equity

No. Complications
No. Errors/mistakes
No. Incidents
Pregnancy rates
Psychological support
Thorough diagnostic phase
Individualized treatment
Access to information
Transparency

Patient-centeredness

Safety

Timeliness

What is Management?
gestão (Port.); administración (Span.)

″ The art of getting things done through and with people in formally organized groups (*H. Koontz*)

″ The group of people that interact in a physical or virtual environment and have the same goal (*F. Bento*)

Q QUALITY **M** MANAGEMENT

Coordinated activities to direct and control an organization with regard to quality

i.   **Service** provided in a standardized way
ii. **Results** analyzed
iii. **Improvements** constantly made

➢ **to guarantee a service of excellence with consistent and stable results**

All we need to do is to put these pieces together using a system…

QMS expresses the organizational structure, policies, procedures, processes and resources used to implement quality management

Mission

Quality policies, objectives & indicators

Document control

Non-conformities, corrective & preventive actions

Auditing, reviews, retention

Improvement actions

Quality manual

Technical manual

Clinical and laboratory SOP manual

Laboratories description

Personnel, job descriptions, responsibilities

Training program

Safety instructions

General rules

Standard operating procedures (SOPs)

Worldwide Tendency to Make QMS Mandatory

Australia	Code of practice for assisted reproductive technology units, Reproductive Technology Accreditation Committee (RTAC)
Brazil	RDC 23/2011, National Agency of Sanitary Surveillance (ANVISA)
European Union	EU directive 2004/23/EG, 2006/17/EG, 2006/86/EG
South Africa	National Health Act 61/2003; Human Tissue Act
USA	CLIA for Andrology laboratories; FDA for cryobiology

Quality Management System

1996 – Androfert established

2000 – IVF Program started

2006 – QMS implementation started

2010 – ISO 9001 certification

2013 – Recertification

2016 – Recertification

ISO* 9001 Model Easily Adapted to ART Units

✓ **Customer service**

✓ **Document control system**

✓ **Personnel management**

✓ **Audits**

✓ **Procedures for detection, registration, correction and prevention of errors and non-conformities**

✓ **Safety (risk management); ISO 9001:2015**

✓ **System to evaluate and control materials and equipment**
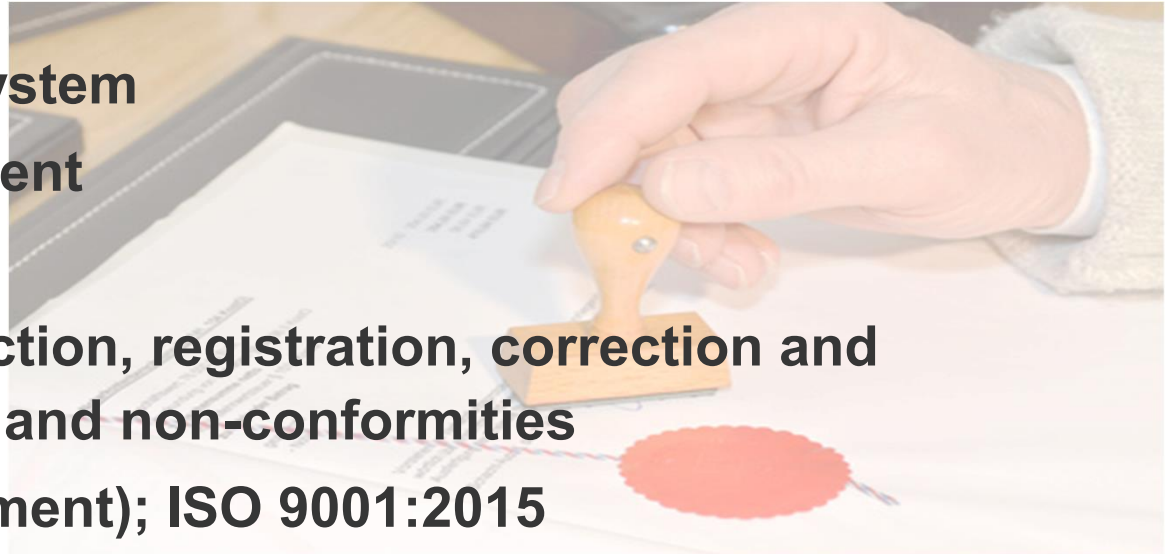
*ISO: International Standardization Organization

Other International Standards

˝ **ISO 15189: Medical laboratories**

  . particular requirements for quality and competence

˝ **ISO 17025:** General requirements for the competence of testing and calibration laboratories

˝ **Clinical and Laboratory Standards Institute (CLSI)**

  . QMS model for health care (HSI-A2)

  . QMS model for laboratory services (GP26-A3)

QMS - ISO 9001

Say what you do and what your requirements are

Mission

QM focus

Show how you do

Process

Show how you ensure you follow what you say you do

Registering & Auditing

Monitoring

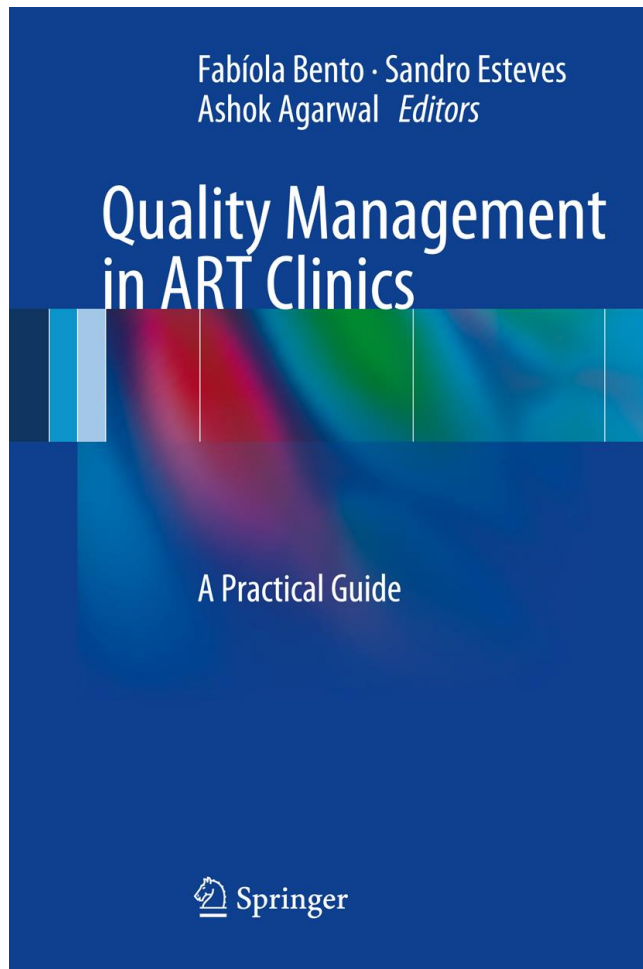**Show what you do to improve what you do**

Continual improvement

ISO 9001 does <u>NOT</u> define the actual quality of your product or service

It helps you achieve consistent results and continually improve the process.

Thus, if you can make a good product most of the time, this helps you make it all of the time.

It's about good business practices.

Fabíola Bento · Sandro Esteves
Ashok Agarwal *Editors*

Quality Management in ART Clinics

A Practical Guide

Springer

˝ **Provides practical know-how on implementing and improving QMS in ART clinics**

˝ **Examples and sample forms easily adapted for the individual clinic**

Quality Manager

Establish unity of purpose and direction of the internal environment

Create an environment where <u>people</u> are fully involved in achieving the organization's objectives

Fabiola Bento, MBE
Quality Manager, ANDROFERT

✓ *Teaches the ISO standards to the whole team*

✓ *Engages the management team so that their work reflect the new concept and is used as an example for the rest of the team*

Main characteristics: Leadership and autonomy

Step 2: Explain Why the Organization Exists

WHO are your clients?

WHAT are the services you provide?

HOW methods, philosophy, objectives, etc.

ANDROFERT

Our mission is to offer counseling, diagnostic and treatment services to men with fertility problems, and offer our associate doctors all the infrastructure and laboratorial services to perform assisted reproductive technology

Quality Management Focus

Quality Policy	Brief, simple and direct statements that define top managements commitment to quality (general quality orientation and basic intentions)
Quality Objectives	Goals of each quality policy (they have to be measurable)
Quality Indicators	How to monitor quality objectives (tools to check if objectives and policies are being achieved)

QUALITY POLICY AND QUALITY OBJECTIVES

POLICY	OBJECTIVE	Indicator	Periodicity	Responsibility	Goal
Guarantee clients Satisfaction	Satisfy clients	Satisfaction questionnaire	Every three months	Manager Assistant	80% of satisfaction
	Satisfy clients	Satisfaction surveys	Every two months	Nurse	Recover 50% of patients
Improve service quality continuously	Improve laboratory performance	Laboratory report	Every two months	IVF Embryologists	See IVF quality program
	Invest in structure and equipment	Investments' plan	Annually	General Manager	See annual report
	Improve QMS	Internal audit report	Annually	Quality Manager	Decrease number of non-conformities
	Improve QMS	Non-Conformities and Preventive Actions	Annually	Quality Manager	Decrease non-conformities and increase preventive actions
	Improve general performance	Management report	Every month	Quality Manager	Improve results
Guarantee staff professional development	Offer periodic training	Training Program and Investment Plan	Annually	Quality Manager	See plans

Processes and Procedures

Any activity or set of activities that uses resources to transform raw material, supplies and labor (inputs) into products or services (outputs)
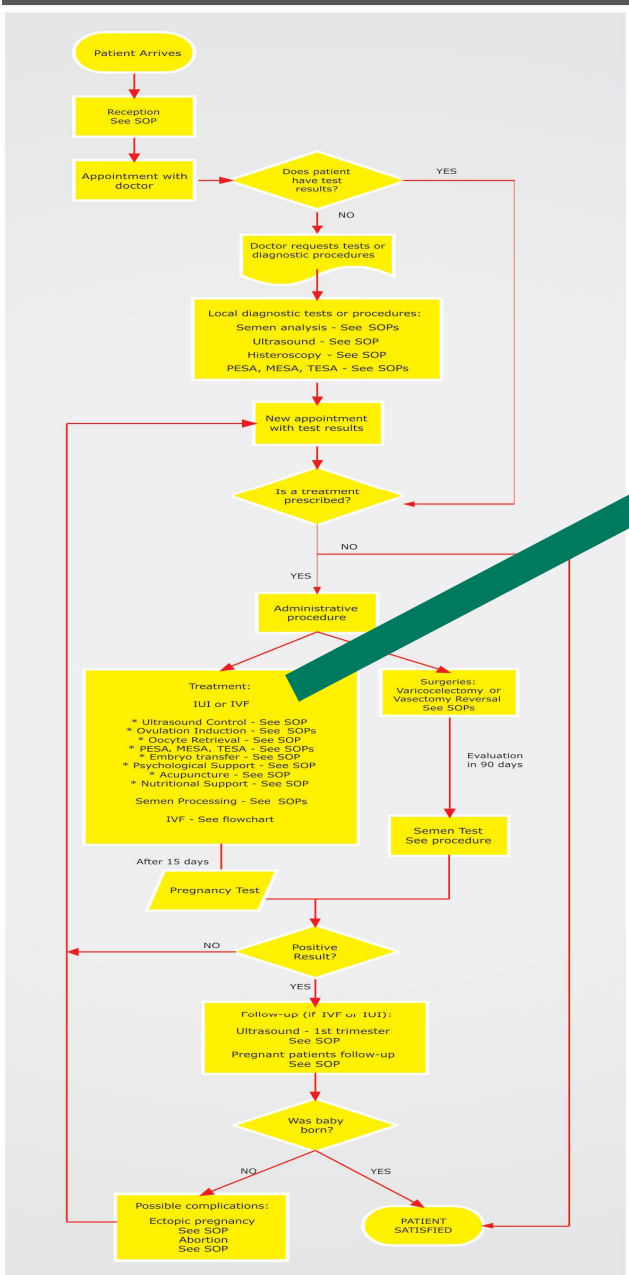
Sequence of steps to execute a task

Important for standardization and replication

- *Identify and standardize all processes and procedures involved in the realization of services provided*

- *Include infra-structure and human resources*

PATIENT PROCESS

Ultrasound monitoring (SOP#1)

Ovulation induction (SOPs #1-8)

Oocyte retrieval (SOPs #9-12)

PESA, MESA, TESA, micro-TESE (SOPs #13-16)

Embryo transfer (SOPs 17-18)

Semen Processing (SOPs 19-23)

Human Resources
an organization's most valuable asset

″ **Job descriptions**

. *Should accurately describe tasks and authorities*

″ **Professional qualifications**

″ **Responsibilities clearly defined**

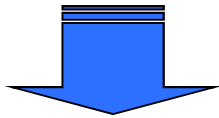. *Importance and role within the organization*

″ **Personnel policies**

. *Ethical issues and moral values*

″ **Induction training and retraining program**
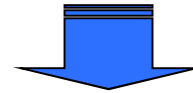
″ **Competency assessment**

Qualified New Employee

Orientation

Job Description

QMS Training Programs

| TRAINING	DEPARTMENT
Mission Statement	All
Quality Policy Quality Indicators and Objectives	All
How to register a nonconformity and corrective actions	All
How to register preventive actions	All
How to describe procedures and processes	All
Procedures/Processes	Individualize by department
How to review procedures and processes	All
Internal Auditors	Only selected staff
Auditing Process	All
Internal Communication	All
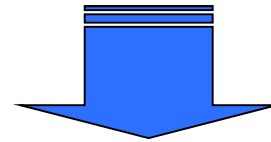
Task-specific Training
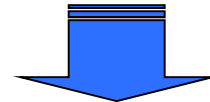
Competency Assessment
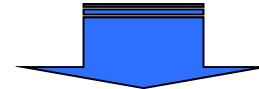
Retraining

Competency Recognition

Competency Assessment Methods

- " **Direct Observation**
  - ➢ Checklists
- " **Indirect Observations**
  - Monitoring records
  - Use of discarded specimens
  - Case studies
- " **Proficiency Program**

QMS - ISO 9001

Say what you do and what your requirements are	**Mission**
	QM focus
Show how you do	**Process**
Show how you ensure you follow what you say you do	**Registering & Auditing**
	Monitoring
Show what you do to improve what you do	**Continual improvement**

Auditing

Objective

Verify conformity

Types

Processes, Procedures, Documents and Records

Quality Actions

Corrective Actions	**Actions taken to correct a non-conformity after detecting it**
Preventive Actions	**Actions taken to avoid a potential non-conformity before it actually happen**
Improvement Actions	**Actions taken to improve the service provided**

ANDROFERT   Início   Pacientes ▾   Agenda   Relatórios ▾   Laboratório ▾   Administração ▾   Configurações ▾   Sair

Registros de Ações do Programa de Gestão da Qualidade   Voltar

Tipo
Selecione o tipo ⬍

Setor
Selecione o setor ⬍

Origem
Selecione a origem ⬍

Data de Abertura
| Início | Término |
| 01/07/2015 | 01/01/2016 |

Filtrar

Data de Abertura	Tipo	Setor	Origem	Data de Implementação	Data do Fechamento	Ciência Gerente Qualidade	Ciência Diretor
15/12/2015	Oportunidade de melhoria	Enfermagem	Reclamação de Paciente	12/01/2016	12/02/2016 Acompanhamento	Fabiola Bento 29/01/2016	Dr. Sandro Esteves 07/04/2016
04/12/2015	Não conformidade	Laboratório FIV-Crio	Detecção Interna	12/02/2016	12/02/2016 Implementação	Fabiola Bento 13/02/2016	Dr. Sandro Esteves 07/04/2016
27/11/2015	Não conformidade	Laboratório FIV-Crio	Detecção Interna			Fabiola Bento 27/11/2015	Dr. Sandro Esteves 07/04/2016
24/11/2015	Não conformidade	Atendimento	Detecção Interna	25/11/2015	12/02/2016 Acompanhamento	Fabiola Bento 07/04/2016	Dr. Sandro Esteves 07/04/2016
14/11/2015	Não conformidade	Laboratório FIV	Detecção Interna	16/11/2015	12/02/2016 Acompanhamento	Fabiola Bento 15/11/2015	Dr. Sandro Esteves 07/04/2016
10/11/2015	Não conformidade	Laboratório FIV-Crio	Detecção Interna			Fabiola Bento 10/11/2015	Dr. Sandro Esteves 07/04/2016
06/11/2015	Oportunidade de melhoria	Laboratório FIV	Detecção Interna	19/11/2015	12/02/2016 Acompanhamento	Fabiola Bento 08/11/2015	Dr. Sandro Esteves 07/04/2016

Monitoring, Measuring and Analyzing

Data collection

Internal and external audits

Registration of quality actions

> Non-conformities, preventive actions, improvement actions, complaints

Satisfaction surveys/questionnaires

QC and QA reports

> Key performance indicators
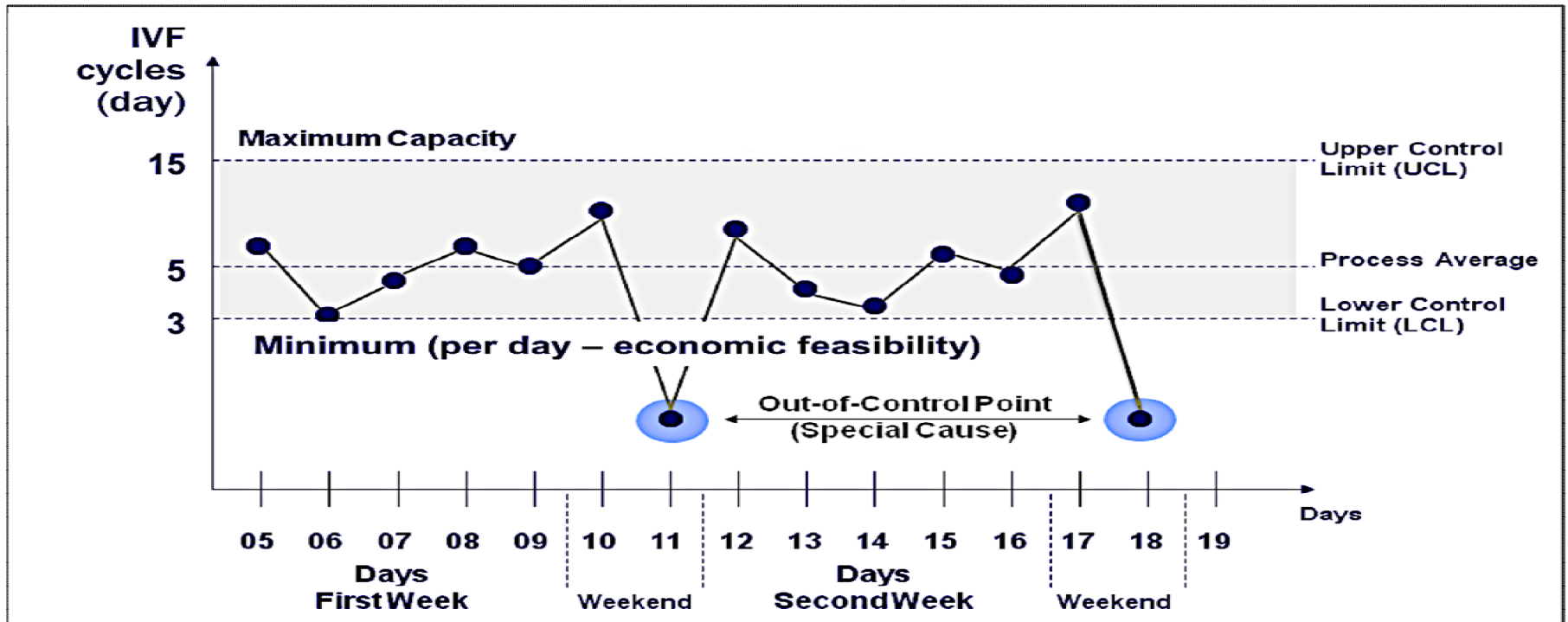
Measuring and Analyzing

Quality Tools

Pareto diagram
Diagram of cause and effect
Control chart
Histogram
Flowchart

Quality Methods

PDCA
Balanced score card (BSC)
SWOT Analysis

Control Chart
Monitor the stability of a process

Androfert Balanced Score Card 2015
(Hierarchized view of the organization's performance QMS)

Category		Metric	Target	Status
Customer satisfaction	Repeat customer	% IVF drop-out after 1st cycle	<50%	25%
	Service	% IVF cycles w/complaints	<5%	2%
Financial	No. IVF cycles	% Annual growth	>5%	7%
	No. tests Andrology lab	% Annual growth	10%	14%
	Payment rate sperm/embryo bank	% clients in debt	<35%	45%
Employee satisfaction	Turnover	2-yr. period	<10%	10%
	Absenteeism	Days year / employee	4	3
Quality	ISO	recertification	approval	approval
	Non-conformities	No. year	reduction	-30%

Balanced Score Card

- **How do we look to shareholders?** (Financial)

- **How do customers see us?** (Customer)

- **What must we excel at?** (Internal)

- **Can we continue to improve and create value?** (Innovation and learning)

Kaplan and Norton
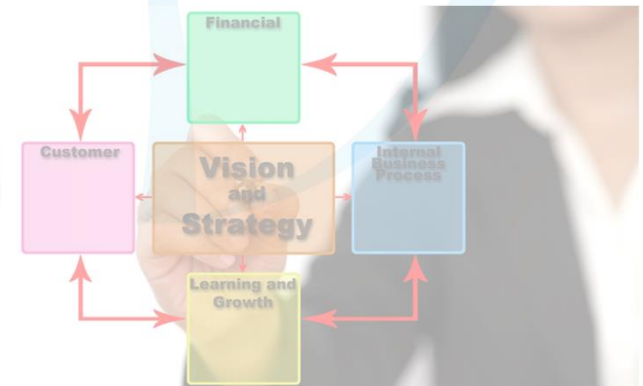
Step 7: Continual Improvement

Set of recurring activities carried out to enhance the ability to meet requirements

- ˝ **Audits (internal & external)**
- ˝ **Self-assessments**
- ˝ **Management reviews**
- ˝ **Implement corrective and preventive actions**
- ˝ **Improvement group**

SWOT analysis diagram

IMPROVEMENT GROUP

PROBLEM	Increase in costs will lead to an increase in treatment prices
QUESTION	How can we diminish costs making treatments more affordable?
PARTICIPANTS	Laboratory Supervisor, Chief Nurse, Chief Secretary, Chief of Cleaning and Maintenance, Manager, Quality Manager
DAY 1	Manager presents actual costs
	Brainstorm what can be changed without affecting quality
	General views and opinions
DAY 2	Practical suggestions of changes that can be made in each department
	Define what will be changed, how and when
DAY 3	Feedback on what was changed and impact on costs
	New changes needed? Restart cycle

SWOT Analysis Summary

Internal Factors	• Appropriate infrastructure • Investment in equipment • Consistent results • Multidisciplinary team • Organization • Personalized care	• Bureaucracy • Constant delays • Internal competition • Lack of internal communication • Bad telephone system
External Factors	• Demand for oocyte cryopreservation • Improve site on the internet offering patient-friendly tools • Marketing opportunities	• Costs of medication • Emphasis on a single type of treatment • Seasonality • A new clinic was open • Legal law suits

STRENGTHS

OPPORTUNITIES

WEAKNESSES

THREATS

SWOT analysis diagram

It is not a

ONE MAN SHOW PRODUCTIONS

| Teach the ISO standard to the whole team | Engage the management team so that their work reflect the new concept and is used as an example for the rest of the team | Identify the processes and procedures involved in the realization of services provided | Standardize all procedures necessary to offer the service provided, writing SOPs and training the team | Create ways to control and guarantee SOPs are being followed without variations | Monitor indicators to continually improve the quality of the service provided | Formally document the system implemented, be surveyed and certified |

Does your organization behave as if it truly believed people were its most valuable asset?

" It requires good people management

" Rewards should be based on QMS behaviors
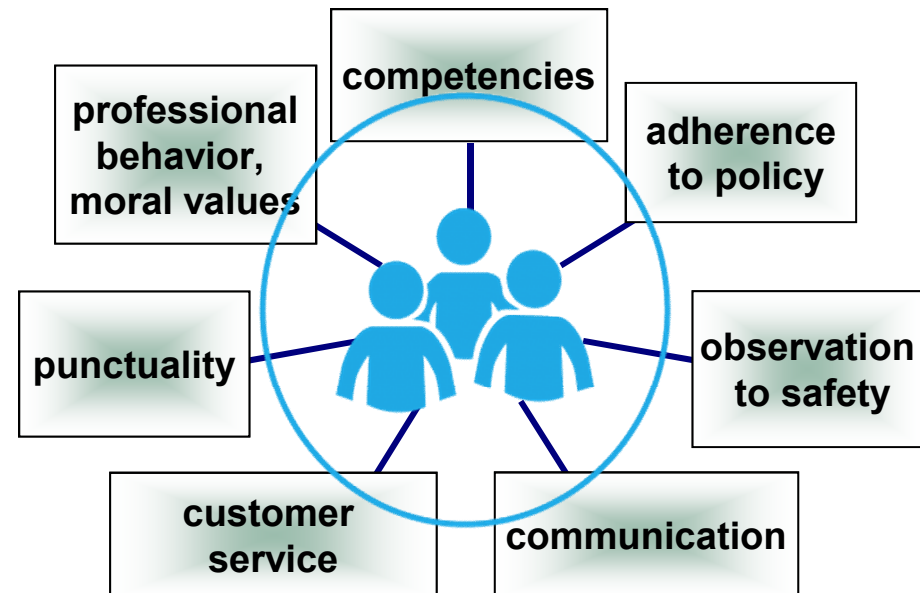
Quality Management in the ART Laboratory
Key Messages

1. Quality goes far beyond a single parameter such as pregnancy rate; robust metrics involving various quality dimensions are essential

2. A QMS like ISO 9001 provides the tools to direct and control an ART Clinic to truly improve the quality of services provided

3. Human resources (and how these resources are managed) critical to success of a QMS

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