INTERNATIONAL FEDERATION OF FERTILITY SOCIETIES

Quality Assurance in Assisted Conception
IFFS Embryology Workshop
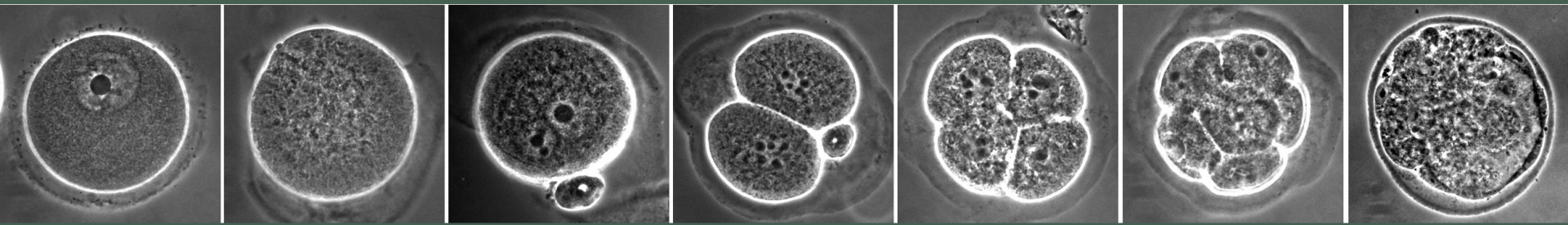### TARTU, ESTONIA
21-23 September 2018

MERCK

Quality Assurance
in
Assisted Conception

Where IVF began…

Where IVF treatment began...

In-house culture medium

- Earle's balanced salt solution
- Diluted with water for injection
- Made from concentrate
- Supplemented with sodium pyruvate and antibiotics
- Added buffer (HEPES or sodium bicarbonate)

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Human embryo development *in vitro* in 1989

Earle's balanced Salt Solution; Bolton et al., 1989
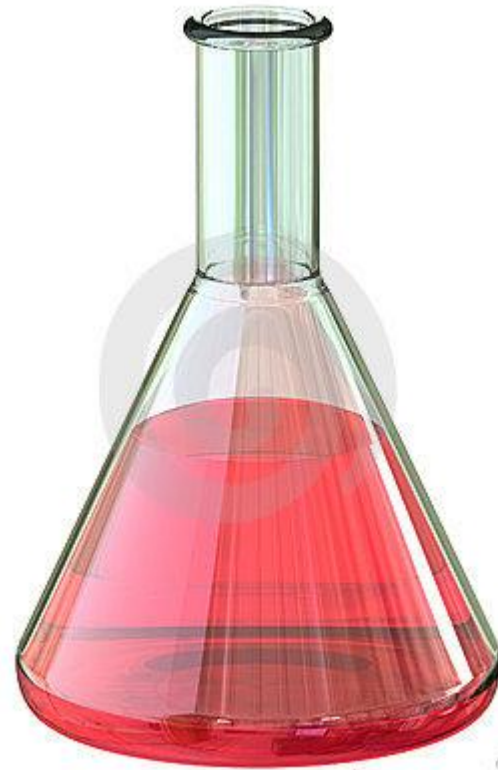
Where we are today

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Comparing 1989 with 2017….

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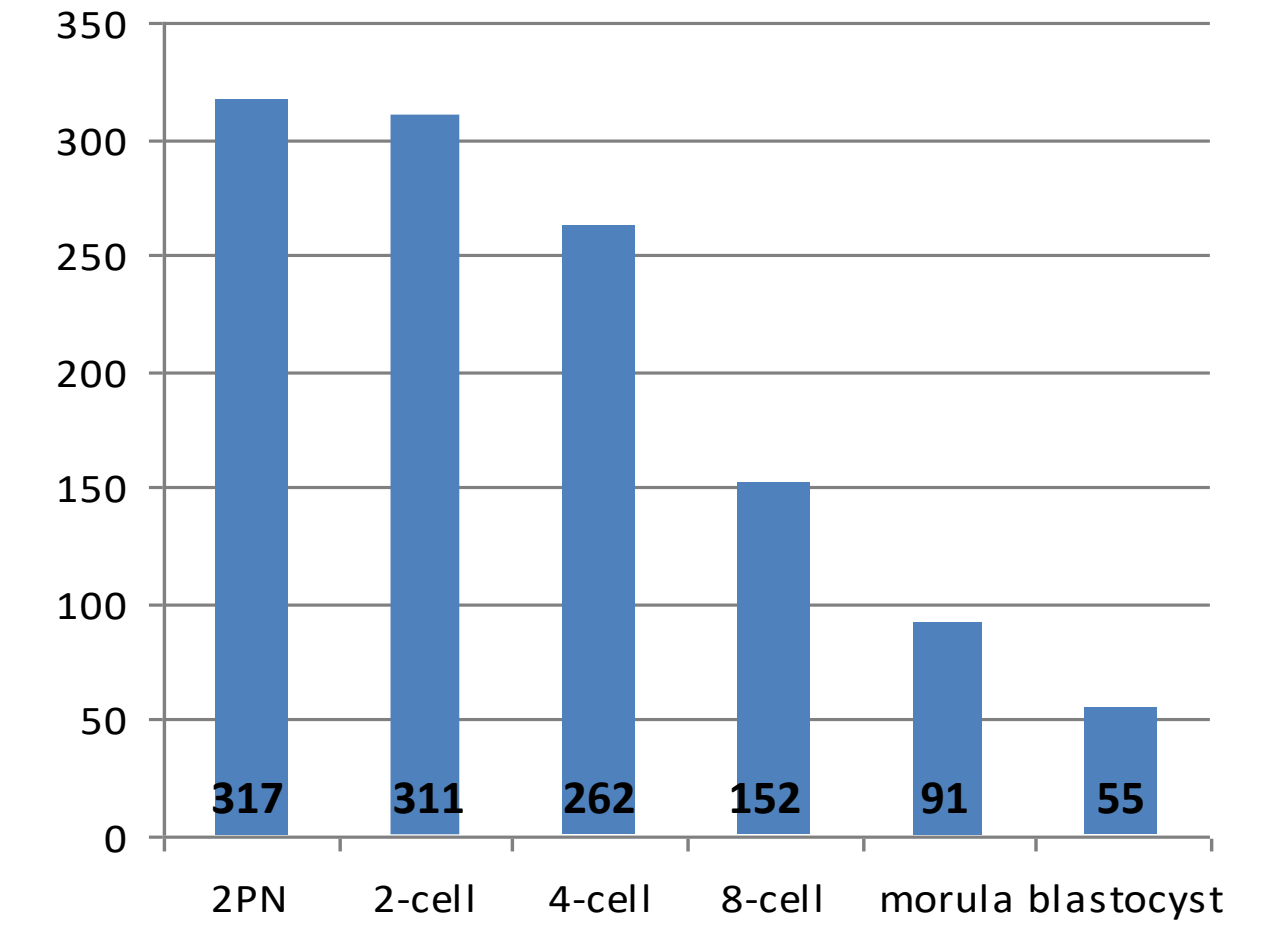**INTERNATIONAL FEDERATION OF FERTILITY SOCIETIES**
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The Quality Management System (QMS)

The QMS encompasses every aspect of the Assisted Conception Unit

It's not just about the lab!

The UK Human Fertilisation & Embryology Authority (HFEA)

23. The quality management system

This guidance note contains:

Mandatory requirements
- Extracts from the HFE Act 1990 (as amended)
- Extracts from licence conditions

HFEA guidance
- Definition of the quality management system
- Establishing, maintaining and documenting the quality management system
- Quality policy and quality objectives
- Quality manual
- The quality management review
- Quality indicators
- Assessing user satisfaction
- Staff suggestions
- Internal audit
- Participating in external reviews, and inter-centre and inter-laboratory comparisons
- Monitoring, evaluation and improvement

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Quality Policy

QUALITY POLICY

██████████████████████ ACU is committed to deliver a service of the highest quality through consistently striving to meet the needs and expectations of our customers.

Requirements essential to our customers are identified and appropriate quality objectives set; which are continuously monitored, reviewed and acted upon to improve the service and results delivered.

The senior management team ensures that the quality policy is communicated to all employees. It is included in new employee training and training on the QMS. It is posted in a key location in the unit to maintain high standards within the ACU.

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Quality Objectives

QUALITY OBJECTIVE(S)

The quality objectives are aligned with that of the ▮▮▮▮▮▮▮▮▮▮▮▮▮▮▮▮
Trust based on public and staff feed back and focuses on the key areas of:

Patient Safety – having the right systems in place to effectively report, analyse and prevent errors, ensuring that our patients receive the safest possible care.

Clinical Effectiveness – providing treatment and care for our patients that produces the best possible outcomes with the most effective use of financial resources.

Patient Experience – meeting our patients' emotional as well as physical needs. This includes being treated with dignity and respect in a comfortable and safe environment, and being given the appropriate information about their care.

Regulatory Compliance – meeting the provisions of the HFEA Code of Practice, as amended, as required by our HFEA Treatment and Storage licence.

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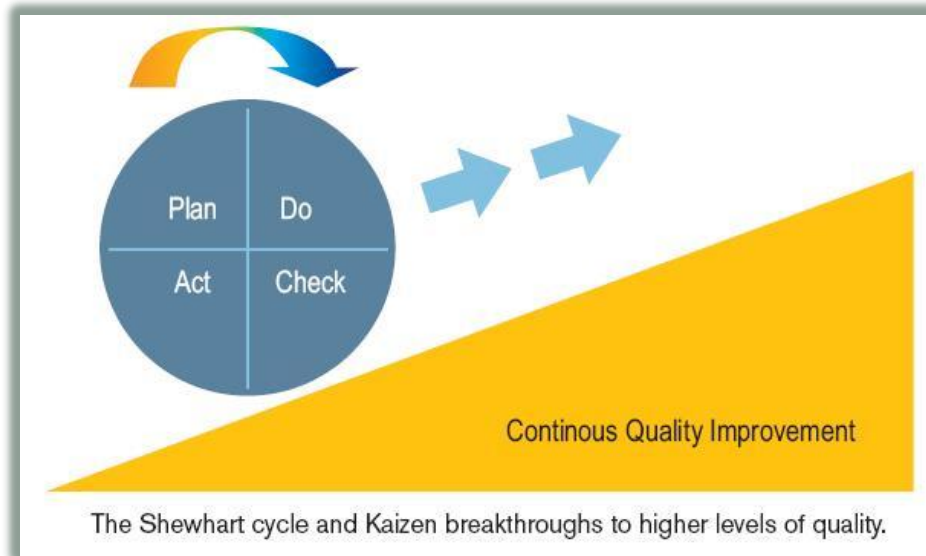
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The Quality Management System

- Quality Control (QC)
  - The process whereby all aspects of the Assisted Conception Unit are monitored and confirmed to be functioning within defined limits

- Quality Assurance (QA)
  - The overall process by which the programme undergoes improvements and corrective actions to maintain or improve its processes

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The QMS Provides a Framework for Improvement & Staff Empowerment

- Capturing Staff Suggestions
- Corrective Action / Preventive Action (CAPA)
- Audit, Root Cause Analysis and Fix
- Incident / Near-Miss Reporting & Management

The Shewhart cycle and Kaizen breakthroughs to higher levels of quality.

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Improve Service User Satisfaction & Enhanced Reputation

- Key Performance Indicators (KPIs) for each discipline within the centre

- Surveys + subsequent CAPA*

- Complaints procedures + subsequent CAPA

- Potential increase revenue to reinvest in services

- Improvement in KPIs e.g. success rates

*CAPA = Corrective Action / Preventive Action

Enhanced Service User Safety

- Effective risk management

- Lessons learned from incidents / near-misses

- Robust clinical / laboratory procedures

- Effective quality control
  - e.g. Witness Checks

Risk Management

RISK ASSESSMENT RECORD FORM
Please refer to the accompanying guidance when completing this form

Type of risk;	Clinical ■	Corporate ☐	Financial ☐	Non Clinical ☐

Section 1: Administrative Details

Name of Assessor:	Job Title:	Date of Assessment:
Kieran H	Quality Manager	11/8/14

Section 2: Activity/Task

Activity /Task

Risk: Patients being treated by IVF develop a potentially dangerous over-reaction to fertility drugs used to stimulate egg production.

Objective the risk is linked to (Identify level of objective: Service, Division, Trust):

Women's Service / Assisted Conception Unit

Area affected:

Assisted Conception Unit

Source of Risk(Background):

Well known potential side effect of IVF

Supporting Evidence:

http://www.patient.co.uk/doctor/Ovarian-Hyperstimulation-Syndrome.htm

Factors the risk contains: *(if for COSHH include route of exposure, length of exposure time and exposure limits)*

Women are deemed more at risk of developing OHSS if:
- They are known to have polycystic ovaries
- Age <30 years

- Identify the risks
- Devise control
- Mitigate them

Maintaining a Competent Workforce

- Controlled QMS documentation provides the best sources of training material
- Training underpins all effective QMS endeavours
- Recorded competency assessment provides a level of Quality Assurance

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The QMS Provides Management Assurance…

- Establishes the framework for continually improving systems throughout the centre
- Brings an element of automation to the running of the Assisted Conception Unit
- Facilitates staff doing the **right thing at the right time**, in order to maximise the best outcome for Patients

QMS Software

The Shewhart cycle and Kaizen breakthroughs to higher levels of quality.
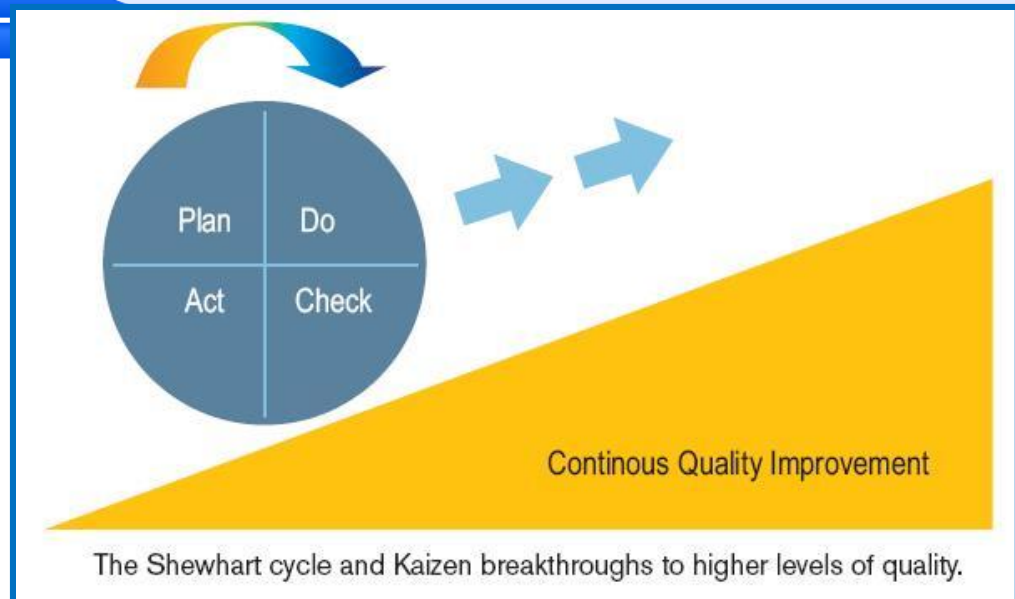
The central role of the laboratory

Gardner & Lane, 2007
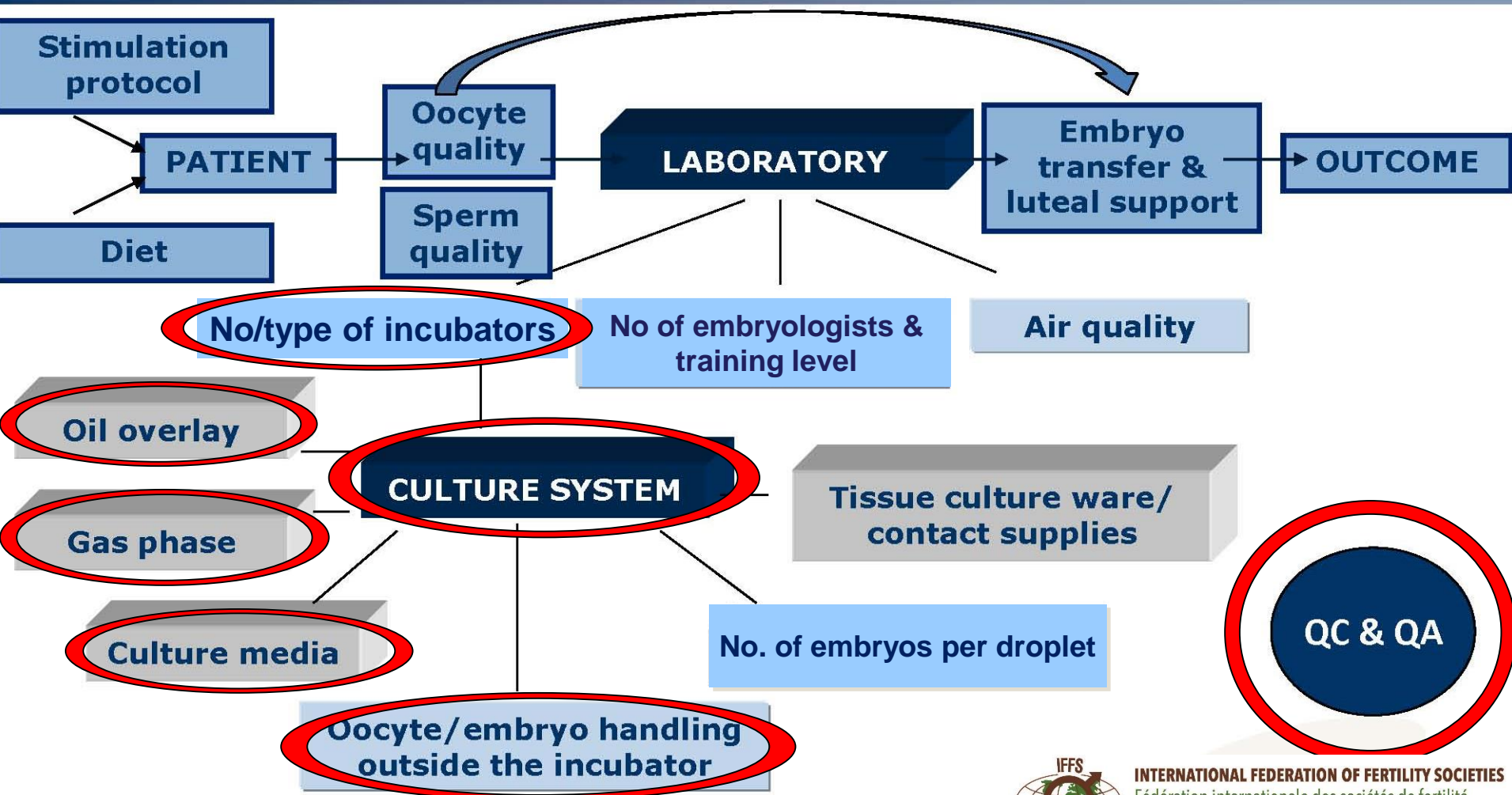
The Quality Management System

- Quality Control (QC)
  - Records should be maintained to demonstrate QC is performed
  - Data may be analysed to identify source of problems and determine solutions
  - Data may be accumulated in several different categories

QC of Personnel

- Number of staff
- Training
  - Competency assessment
  - Adherence to SOPs
- Performance
  - KPIs
  - Process audit

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QC of Procedures

- Written SOPs for every procedure
  - Step-by-step description of procedure
  - Materials and equipment listed
  - Calculations described
  - Limitations of techniques listed
  - Annual review
  - Version control

QC of Equipment

- Validated
- Operate within defined limits
  - Tolerable limits set
  - Daily QC checks; regular validation
    - Temperatures
    - Gases
  - Regular review of records
  - Out of range values trigger corrective actions

QC of consumables

- CE marked
- Batch records

QC of Air Quality

- Particle counts
- Settle plates

Process Validation

- Regular Process Audit
- Confirm uniformity and reproducibility between practitioners
- KPIs

Quality Management
in the Assisted Conception Unit ensures...

1. Operation Within Regulations

2. Framework For Improvement

3. Increased Patient Satisfaction

4. Enhanced Service User Safety

5. Empowered Staff

6. Enhanced Reputation

7. A Competent Workforce

8. Management Assurance

9. Continued Success

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