

European Society of Human Reproduction and Embryology



COURSE 1

Paramedical Pre-congress Course

**1 July 2007
Lyon, France**

PRE-CONGRESS COURSE 1

Paramedical Pre-congress Course

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PRE-CONGRESS COURSE 1 - PROGRAM

Paramedical Pre-congress Course

Chair: H Birch (UK) and D Molero (E)

09.00 – 09.15: Introduction - **H. Birch (UK)**

09.15 – 10.00: What is quality? - **R. Janssens (B)**

10.00 – 10.45: Learning from incidents “No blame culture” - **S. Sullivan (UK)**

10.45 – 11.15 *Coffee break*

11.15 – 12.00: Effective use of patient feedback - **L. Blonk (NL)**
Questionnaires - Different techniques
Practical application

12.00 – 12.30: *Discussion and feed back* - **R. Janssens (B)**

12.30 – 13.30: *Lunch*

14.00 – 14.30: Role of the IVF Midwife in France 8 years on - **V. Blanchet (F)**

14.30 – 17.00: Visit to an IVF Unit



What is quality?


Ronny Janssens


 Universitair Ziekenhuis Brussel
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Learning objectives

- Understand the definitions of quality
- Understand the Deming principle for continuous improvement
- Learn what total quality management is and understand the consequences in our daily practice
- Understand how we measure quality


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Outline

1. **Definitions**
2. Continuous improvement
3. Quality management
4. Measuring quality
5. Conclusions

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Quality = superiority of a product?



Juran:
Quality is fitness for use

In manufacturing:
conformance to specifications

Quality (ISO 9000:2000 3.1.2)

'the degree to which a set of inherent characteristics fulfils requirements'

TRANSLATION:

'an infertile patient with bad semen parameters has a 'requirement' for ICSI...'

The inherent characteristics are that the semen analysis is done in an accurate manner and be properly interpreted, that the ICSI is done by trained staff with good equipment....

Requirements (ISO 9000:2000 3.1.2)

Need or expectation that is stated, generally implied or obligatory

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Requirements (I)

- Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting the standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.
- Directive 2006/17/EC of the European Parliament and of the Council of 8 February 2006 as regards certain technical requirements for the donation, procurement and testing, of human tissues and cells
- Directive 2006/89/EC of the European Parliament and of the Council of 23 October 2007 as regards certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells

• **National legislation – professional standards**

- UK: Human Fertilisation and Embryology Act 1990
- NI: CCKL - KLEM
- Fr: Agence de biomedicine

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Requirements (II)

ESHRE guidelines for good practice in IVF laboratories
Luca Gianaroli, Michelle Plachot, Roelof van Kooij, Safaa Al-Hasani, Karin Dawson, Anick DeVos, M.Cristina Magli, Jacqueline Mandelbaum, Jacqueline Selva, Wouter van Inzen.
Human Reproduction, Vol. 15, No. 10, 2241-2246, October 2000.

Standards

- ISO 9000:2000 Quality management systems – Fundamentals and vocabulary
- ISO 9001:2000 Quality management systems – Requirements
→ Certification
- ISO 15189:2003 Medical laboratories-Particular requirements for quality and competence
→ Accreditation

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customer satisfaction ISO 9000:2000 3.1.4



- 'customer's perception of the degree to which the customer's requirements have been met'.
- The 'customer' can be a patient, a donor, a recipient of donations or persons undergoing treatments using their own gametes.

Take home message 1

Quality = To meet patients expectations

- No (identification) errors
- Safe and efficient procedure
- Competent staff
- Good equipment
- Cheep
- High success rates
- ...

Quality in 4 steps

1. Read, read again, understand and accept the standards
2. Say what you do, do what you say...
3. Prove it - change from oral culture to written culture
"What is not written does not exist"
4. Improve it - Implement a quality management system

↓
The Deming wheel (Plan – Do –Check – Act)
=continuous improvement
Reoccurring activity to increase the ability to fulfill requirements (ISO 9000:2000 3.2.13)

Outline

1. Definitions
2. **Continuous improvement**
3. Quality management
4. Measuring quality
5. Conclusions



Take home message 2

Quality = a positive way of dealing with mistakes!

Dont say: « it is bad » - negative

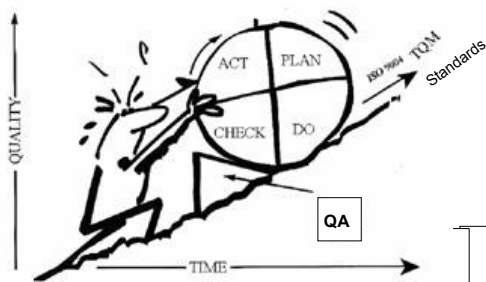
Say: « it can be done better » - positive

Continuous improvement

Reoccurring activity to increase the ability to fulfill requirements (ISO 9000:2000 3.2.13)

Establishing objectives and quality indicators using evaluation activities including audit findings and user satisfaction surveys, management reviews and other means, to find opportunities for improvement that may require corrective or preventative action.

Take home message 3: Quality = continuous improvement




Outline

1. Definitions
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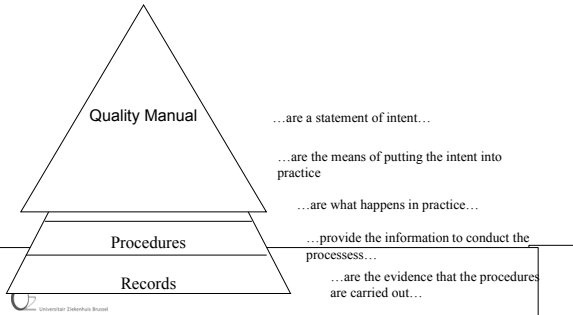
Quality management system

- **Management system to direct and control an organisation with regard to quality (ISO 9000:2000 3.2.3)**



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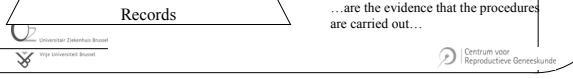
The quality management system



Quality Manual ...are a statement of intent...
 ...are the means of putting the intent into practice
 ...are what happens in practice...

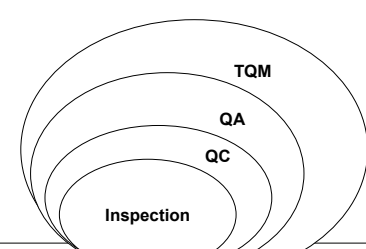
Procedures ...provide the information to conduct the processes...

Records ...are the evidence that the procedures are carried out...



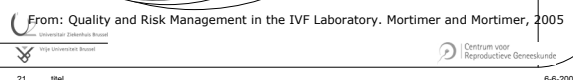
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Total Quality Management



- Medical and scientific standards
- Responsibility
- Duty of care
- Ethics
- Customers expectations
- Legal obligations



From: Quality and Risk Management in the IVF Laboratory. Mortimer and Mortimer, 2005



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TQM in practice

- **Documents - SOPs**
- Investments - maintenance
- Staff –training
- Validation
- Quality control
- Quality assurance
- Idea, complaint, non conformity
- Audits
- Preventive and corrective actions
- Management review

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Procedures – documents

SOPs

- as primary training resources
- To control process details
- Standard layout

Forms



- Data collection
- Process control
- Patienten ID verification
- Operator ID & witnessing
- Materials logging

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Accomodation



- Limited and controlled access
- No toxicity (non toxic paint – glue)
- Easy to clean
- Reduced light – no windows
- Continuous power supply– UPS
- HVAC – HEPA – positive pressure

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The environment

- **Monitoring of**
 - Air change frequency
 - Particle count
 - Microbiological contamination
 - Relative pressure
 - Temperature – humidity
- Air lock
- Protective clothing



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WWW

Who – What – When?

Responsibility



- Functions
- Job descriptions
- Task assignments

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How to avoid errors?

- Semen: identification - signatures
- Culture: double identification system with unique identifier (c-number)
- Use of disposable materials
- Separation in place - time
 - Gametes/embryos of one patient at a time
- Double witnessing
 - OPU – identification of culture dishes –sperm preparation - insemination (IVF) – cumulus removal – ICSI – embryo replacement – freeze-thawing – storage in LN₂ – changes of culture medium

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Incubators

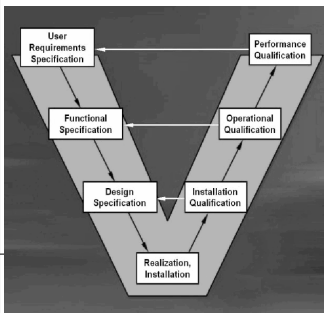


- Measurement of real CO₂ concentrations
- Once a week
- Calibrated measuring device
- Or permanent monitoring

Laboratory equipment

- Back-up of critical equipment
- Permanent power supply
- External alarm system (storage tanks – incubators -)

Validation



ISO 15189 §5.5.2
“The laboratory shall use only validated procedures for confirming that the examination procedures are suitable for the intended use”

Temperature

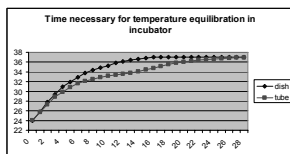
Pickering S.J., Braude P.R., Johnson M.H. et al. (1990).
Transient cooling to room temperature can cause irreversible disruption of the meiotic spindle in the human oocyte. *Fertil Steril*, 54, 102-108.
- 1°C cooling = irreversible damage to meiotic spindle

Wang W.H, Meng L., Hacket R.J., Odenburg R., Keefe 2001.
Limited recovery of meiotic spindles in living human oocytes after cooling-rewarming observed using polarized light microscopy *Hum. Reprod*, 16: 2374-2378 (Polscope)

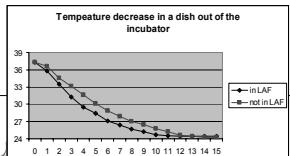
Depolarisation of spindle, oocytes are more sensitive than embryos

IVF: $37.0 \pm 0.5^\circ\text{C}$

Temperature



RT – 37°C: 20 min



Cooling: 0.5°C/min

EQC

-Internet based Quality Assessment system QAP-online
(WWW.fertaid.com)

- Subscription based
- Schemes for andrology – embryology – follicular measurements...
- Images or videos, participants are asked to rank and score zygotes/embryos



Monitoring of critical process parameters

Manual registration

- labour intensive
- time consuming
- Limited added value

Automatisation

- Complex installation
- continuous measurements
- internal and external alarms






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Nonconformity

Non-fulfilment of a requirement (ISO 9000:2000 3.6.2)



- Any failure to protect the quality and safety of gametes or embryos during donation, procurement, testing, processing, preservation, storage and distribution processes is a major 'nonconformity' requiring immediate investigation and corrective action

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Problem solving

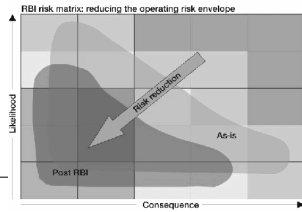
- Define the problem
- Collect data
- RCA
- Define solution to prevent reoccurrence
- Implement
- Measure effectiveness

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Risk analysis

- Why waste our time, that's just so unlikely?
- Identify – analyse – evaluate and rank – treat
(C= R x L)



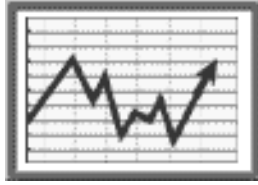
Internal audits

- Plan – Do – Check – Act
- Internal audits on all elements of QMS
 - Corrective and preventive actions
 - Monitor efficiency

Outline

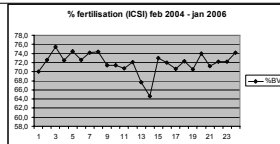
1. Definitions
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Measuring quality: benchmarks

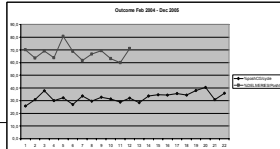


- a point of reference for a measurement
- the process used in management in which organizations evaluate various aspects of their processes in relation to the best practice, usually within their own sector

Benchmarks



- Reliable
- Robust
- Routine





Benchmarks: reference population

- Stratification according to:
 - Age: ≤ 36
 - Stimulation: >5 COC
 - Sperm origin: ejaculated only
 - Treatment: IVF – ICSI, no PGD
 - Rank of trial: 1 or 2nd cycle
- Statistical robustness
 - Per trimester
 - Per year

Measuring quality: « you can't control what you can't measure »

- Oocyte maturity
- Fertilisation rate
- Cleavage rate
- ...



- Incident reports
- Complications
- Equipment failures
- Complaints
-

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Conclusions: Quality is

1. To meet patients expectations
2. A method to deal with mistakes
3. A process of continuous improvement
4. Measurable


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Learning from Incidents


01 July 2007
ESHRE
Lyon

Stephanie Sullivan
Head of Clinical Governance and Patient Safety
Human Fertilisation and Embryology Authority




History

- HFE Act 1990
- Code of Practice
- Toft Report
- Incident Reporting System
- Alert System
- Grading System



Role of HFEA in incident management

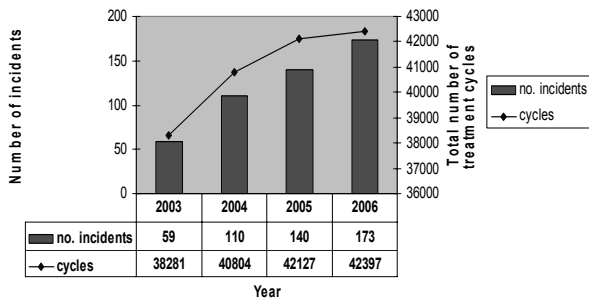
- UK hub for ART incidents. Identify trends, patterns and underlying risk factors
- Share lessons across sector
- Help develop understanding of causes of incidents to inform policy
- Monitor clinics' compliance with policies that promote safety – at inspection



Definition of incident

- CoP 2.24 "...any event, circumstance, activity or action which has caused, or has been identified as potentially causing harm, loss or damage to patients, their embryos and/or gametes, or to staff or a licensed centre."
- Near Miss - serious incident that had the potential to cause an adverse event but fails to do so because of "good luck" or because it is intercepted

Incidents reported per year against total treatment cycles



Incident Categorisation Laboratory

- Laboratory operator (= human error)
eg damage to gametes or embryos whilst handling
- Laboratory process. Failure to follow lab protocols or HFEA Act/CoP.
eg screening
- Laboratory equipment
eg batch variations, equipment malfunction

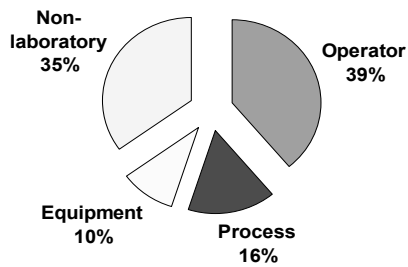
» Cont/d

Incident categorisation Non-Laboratory

- Clinical - patient interface
- Breach of confidentiality
- Consent
- Legal - allegation of illegal activity
- Any Breach of the Act or failure to comply with CoP



Sample of incidents by category



Risk scoring tool

- Severity v probability of recurrence (5x5)
- Grade A (15-25 Severe)
- Grade B (6-12 Moderate)
- Grade C (1-5 Minor)
- Near Miss scored as above
- Scores may be adapted



Subjective Probability



GRADE A

- Incident Inspection necessary.
- Final report to License Committee
- Incident and trend analysis

GRADE B

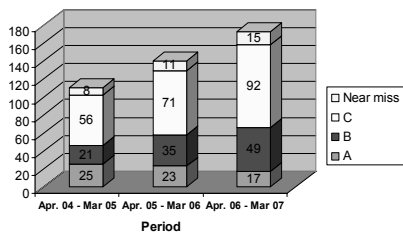
- Incident investigation required. May require site visit
- Incident and trend analysis

GRADE C

- Add to database
- Acknowledge and close.
- Trend analysis



Rise in reported incidents, decrease in severity



Learning from Incidents

Requires:

- Openness, transparency and trust
- A systematic approach to managing incidents
- Grading or sieving system
- A just culture
- Clear demarcation between incident and disciplinary policies
- Analysis/investigation
- Dissemination of lessons learned
- Monitoring at inspection



Consider ALERT?

- Examine results of investigation of incident.
- What lessons can be learned?
- Could knowledge reduce opportunity for similar incident reoccurring?
- Will ALERT allow opportunity for clinics to develop or upgrade their protocols to avoid similar incident?



Purpose of an ALERT

Is to **share** with clinics:

- Information
- History
- Contributory factors and/or root causes
- Actions/Recommendations
- Responsibility of PR to ensure ALERT disseminated to staff and appropriate changes made and monitored
- Provides focus for inspection process



23 HFEA Alerts 2003-07

Include:

- Witnessing of gametes and embryos
- Transport of gametes and embryos
- Use of off label equipment
- Power supply and critical equipment
- Micromanipulation
- Storage of unscreened and screened samples



Conclusion

Incident reporting is evolving:

- Supports patient safety
- Requires good leadership
- Open process built on trust
- Beware of hindsight bias
- Shared learning from process failures and accidents through the anonymised ALERT process
- Encourages subsequent improvement in practice
- Recognise good reporters



Midwife's role in an infertility centre in France

Valerie Blanchet, Midwife
Reproductive Medicine Unit
Hopital Cochin
Paris
France

Learning objectives

- ✓ Provide an overview of the midwife participation in an In Vitro Fertilization (IVF) centre in France
- ✓ Share experiences and discuss about the place of the midwife in Europe especially in IVF centre
- ✓ Discuss on propositions for the future

Summary

In France, ART is performed in obstetrical and gynaecological units and midwives are considered as a medical and not a paramedical profession. They can participate to all the activities, including gynaecology and infertility, because of their well-recognized scientific skills, technical capabilities, and relational qualities. The midwife's role can be summarized in 4 main parts, (1) centre coordination, (2) clinical activity, (3) centre administration, and (4) Clinical research and results evaluation. These different roles will be detailed in the course.

Introduction

The first French IVF baby was born in The Hospital Antoine Béclère (Clamart) in 1982 and, since that date, more than 150,000 children have been conceived through ART (Assisted Reproduction Technology) in France. ART is regulated by a law, since 1994 (revised in 2004), and each clinic has to be authorized by the Ministry of Health. Currently, 100 clinics have got this authorization. One of the characteristics of ART is that the clinic activity has been developed and is performed by gynaecologists, mainly in obstetrical units. In these units, Midwives play an important role, primarily devoted to delivery, but more and more enlarged to all gynaecological activity. This position is reinforced by the fact that, in France, midwives are considered as a medical profession, allowed to make prescriptions, and not as a simple paramedical activity. Moreover, they are the natural professional partners of the obstetrician.

The midwife's role relies on her well-recognized scientific skills, technical capabilities, and relational qualities. This is evident in the delivery room, where she has both to insure a healthy birth and to help the couples to live this experience. This can also be understood at the previous step, when couples have problems to become pregnant, where midwife finds her place in the medicalisation of procreation, both on the technical plan and as a counsellor for couples in this long way to the conception.

My own experience has been acquired since 1993, when I began to work in the ART unit in the hospital Antoine Bécclère and relies on my activity since that date, on a full-time position, in this unit until 2003 and, then, in the Cochin reproductive unit.

The midwife's role can be summarized in 4 main parts.

1. Centre coordination
2. Clinical activity
3. Centre administration
4. Clinical research and results evaluation

The Midwife role in a French centre

1 Centre coordination.

The activity of an ART centre relies on the work of many people, involved from the infertility diagnosis to the treatment itself and its outcome. People can be classified in 3 categories, depending on their activity

- Clinical activity:
 - Obstetrician-gynaecologists
 - Ultrasonographers
 - Andrologists
 - Paediatricians
 - Midwives
 - Psychotherapists
 - Nurses
 - Auxiliary nurses
- Biological activity
 - Biologists
 - Embryologists
 - Technicians
- Administrative work
 - Secretaries,
 - Archivists
 -

Thus, there is a need for a real multidisciplinary collaboration, and for a good organization, in order to have all the information complete and to take the right decisions. Moreover, couples are often suffering from their infertility since long time, and they need to be welcomed, reassured and properly guided in their path. They are often confused, asking for explanations and information. They suffer from stress and anxiety and hesitate to directly ask questions to the doctors.

The midwife must act as a go-between both at the unit level with the different professionals, and between the unit and the patients. Several means can be organized.

- Creation of a dedicated phone line, with an answering machine, allowing couples to leave messages at any time that can be answered by the midwife. She can contact them, reassure them, give to them all the needed medical explanations with a more adapted lay-language, and, if necessary, organize an individual meeting. Moreover, the couples usually know that a midwife is easier to meet in the hospital than doctors at any stage of their treatment.
- Organization and animation of regular information meetings for couples, that is compulsive in the French law before the first cycle.

- Individual meetings before the first cycle, to detect the couples potentially subject to psychological or understanding difficulties. These meetings are also a good opportunity to collect the information sheets that they have to sign.
- Organization of staff-meetings. These meetings can have 2 aims, one to discuss each individual case, and the second, to discuss on a more general level, either to improve the activity or for medical training. In these cases, it can be interesting to invite external speakers.
- Programming attempts and the beginning of the medical treatments

2. Clinical activity

Several clinical activities can be made by midwives

2.1. Ultrasonography (which needs specific training)

- Ovulation induction monitoring,
- Early pregnancy diagnosis
- Spontaneous abortion and ectopic pregnancy detection
- First trimester abnormalities detection

These examinations constitute favourable opportunities to discuss with the couples. It is important to describe the findings to the couples and it is sometimes necessary to announce the cycle failure.

2.2. Daily staff-meetings

The midwife has to participate on a daily basis, and this is particularly positive if she makes ultrasound. She can give her opinion, help to interpret the biological dosages and participate in the decisions.

This is very important because, later on the day, she will have to contact each couple to deliver the staff decisions and to explain them, which sometimes need long discussions. In particular, a decision to stop the treatment, which is lived as a failure by the couple, must be very carefully explained. Moreover, it is sometimes necessary to orientate the couples in other directions, with the help of psychologists.

2.3. Embryo transfers

In some occasions, a midwife can make the embryo transfer. This is a relatively simple clinical gesture, but needs application and specific training. Also, it is very important to warmly welcome couples before the transfer, because it is a very stressful moment. Relaxing women with sophrology training before or after transfer shows a real benefit for them. To be present gives the opportunity of giving the last explanations on the luteal phase treatment and to organize the follow-up of the cycle and the potential pregnancy.

2.4. Obstetrical consults

This allows following the treated patients, which can be nicely viewed by the couples, especially in the hospital where consults are often impersonal. Moreover, it is a good sign for the couples who know that midwives usually only follow the normal pregnancies.

3. Centre administration

3.1. Welcome organization

As it was discussed above, infertile couples have many steps to go through in an ART centre, with different acting people, and they are subject to stress and anxiety. All this implies a perfect organization, with a warm welcome, to help them to decrease their stress, to give them confidence in the medical organization and not to lose time. Moreover, this organization is also necessary for the people working in the unit, in order to give them a good understanding of their own role and of their co-workers role and of the importance of each. This is a topic on which the midwife can play an important role, with its situation between doctors and paramedical or administrative workers.

3.2. Regulatory documents

Couples have several consent forms to fill in, for the IVF technique, the embryos freezing process, the embryos number to be replaced, for clinical studies, etc. Each of them needs careful and time-consuming explanations, which is often difficult to get for the doctors. The midwife can play an important role at this level.

Every year, in France, centres have to report their activity summary to the National Regulatory Agency (Agence de Biomédecine). In this summary, it is necessary to get information on all the pregnancy issue and the neonate outcome, which, very often, implies to contact the couples. There is also a need of careful checking to all the data, which necessitate a “medical eye”. The midwife is probably the most appropriate person to control this work.

3.3. Quality control, Iso9001 accreditation

In ART, there is a general move towards an increase of quality, which necessitates reproducibility. Thus, more and more centres have undertaken an Iso 9001 accreditation process. This accreditation relies on an overall analysis of all the processes performed in the centres, including administration, explorations, treatments, and biological activity. There is also an important possible for midwives, because of their integration between all the participants, in collaboration with doctors, biologists and all the staff.

4. Results evaluation and clinical research

4.1. Database management

A complete, well-organized and accurate database is essential for a centre, in order to follow its activity, its results and to perform clinical studies. Moreover, it is also very important to be able to give easily good quality reports to the regulatory authorities. The midwife role is not to really develop the database, which relies on computer engineers, but both to help them, in conjunction with doctors and biologists, to make a database useful for the centre. The second, and not the least, role is to check at the data accuracy and validity, even if other people enter the data. This validation need a medical eye that, very often, doctors have not the time to give.

4.2. Evaluation Statistics

Regular evaluation of the practice and results is essential for keeping and improving the medical quality. It is absolutely necessary to detect all results drops, and to analyze their potential explanations among the couples' characteristics, medical

treatments or biological activities. The midwife can play a role both in maintaining the database quality and in analyzing and presenting the results. This needs a specific training, but can be of great interest for her.

4.3. Clinical research

Each ART clinic can be interested in medical and biological research. This research relies on ideas and objectives, on a good database and on the incorporation of specific data. Moreover, it is usually necessary to get the patients agreement, with an informed consent. This is also a specific place where a midwife can play an important role.

I have personally participated in many studies, of which three have been already published.

- Perinatal outcome and follow-up of 82 children aged 1-9 years old conceived from cryopreserved embryos (Human Reprod 1996).
- Follow-up of a cohort of 422 children aged 6-13 years conceived by in vitro fertilization (Fertility and Sterility 1997).
- Ethical and psychological aspects of selective embryo reduction (Reproduction humaine et hormones 1997).
- Follow-up of oocyte donors (Gynécologie, Obstétrique et Fertilité 2005).
- The long story of couples requesting in vitro fertilisation in Ivf centres (La revue Sage Femme 2006)

Some other are in the publication process:

- Womens's views on friendly IVF

I have presented the results of this last study in an oral communication at the 10th World congress on IVF

Several of these studies were made by phone interviews with a questionnaire and the interviewed patients always welcomed me. It often constituted an opportunity for them to discuss on their treatments, their feelings, their problems or their happiness.

There are many other projects and this participation to studies and to publications is very stimulating for a midwife.

Discussion and new propositions

ART is more and more used to cure infertility, in France as in the World, even if it is difficult to determine if the reason of this increase is due to an increase of infertility itself, or of impatience. However, the mean infertility duration before ART is still around 5 years, where spontaneous fecundity is 0.4% on average, whereas the mean delivery rate per OPU is around 20 % (in France). ART relies on very sophisticated techniques, and is strictly regulated. That reinforces the role of a midwife who, with her technical and medical competences and her relational qualities, can play a unique role of coordination.

ART needs advanced medical and biological research to progress, which is very time-consuming for the doctors, who often lack time to discuss with the patients. The midwife is a useful partner to satisfy the patients' need for discussion and explanations. Moreover, midwives are hope-bearer, because their profession is related to pregnancy, birth, and child. She can be a confidant for women and couples. She is used to hear and to understand the couples' questions pain and problems.

A specific preparation to ART could be proposed, on the model of the preparation to delivery and birth. This could be done in 3 to 4 sessions, a few weeks

before the first cycle, with small groups. This would allow couples to have the opportunity to raise question, to share difficulties and problems to speak together and with the midwife, to have a deeper thought on fertility, childbearing, and treatments. It also would help women to fit better with the changes in their body due to the treatments and, finally, to be better prepared to the difficulties and also to the risk of failure. This needs to be developed.

Conclusion

Thus, the midwife has a lot of potential roles in ART, related of its skills. These roles are important both for the patients and for the staff, and it may be necessary to have several of them in an important centre to fill all of them, which is the case in my hospital.

Since 2005, a medical congress named SMR (Medical Reproductive Society) invite midwives for communications. It's for us an opportunity for meeting together and perform our knowledge, and also to be recognize like a real partner.

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