Nordic Fertility Society

# Quality Guide

Checklist for ART Clinic and ART laboratory

Yes, not-applicable, No

| CLINICAL CHECK LIST | Yes | n-a | No |
|---|---|---|---|
| **PATIENT INFORMATION** | | | |
| Is there a printed patient information on: | | | |
| Ovarian Stimulation? | | | |
| AIH - Artificial Insemination Homologous? | | | |
| AID - Artificial insemination Donor sperm? | | | |
| IVF ? | | | |
| ICSI ? | | | |
| MESA/TESE? | | | |
| Cryopreservation? | | | |
| Egg donation? | | | |
| Embryo donation? | | | |
| Surrogacy? | | | |
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| **INFORMATION ABOUT RESULTS** | | | |
| Does the information for IVF/ICSI describe the volume of activities? | | | |
| Does the information describe results as births per completed cycle? | | | |
| Does the information for IVF/ICSI explain patient selection criteria? | | | |
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| **INFORMATION ON RISKS** | | | |
| Does the information indicate: | | | |
| The risk of hyperstimulation OHSS? | | | |
| The risk of infection or haemorrhage? | | | |
| The incidence of miscarriage? | | | |
| The incidence of ectopic pregnancy? | | | |
| The incidence of multiple pregnancies? | | | |
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| **COST** | | | |
| Is cost for all procedures clearly stated? | | | |
| Does it state the reimbursement policy? | | | |
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| **WAITING LIST** | | | |
| Are waiting list regulations, if there are any, explained? | | | |
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| **COUNSELLING** | | | |
| Is there professional psychological counselling available? | | | |
| Is clinical counselling available before treatment? | | | |
| Is clinical counselling available after treatment? | | | |
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| **INFORMATION ON STAFF** | | | |
| Is the medical staff presented in the patient information? | | | |
| Is the nursing staff presented in the patient information? | | | |
| Is the secretarial staff presented in the patient information? | | | |
| Is the laboratory staff presented in the patient information? | | | |
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| TREATMENT SCHEDULE | | | |
|---|---|---|---|
| Are there written treatment schedules for: | | | |
| Ovarian stimulation/Insemination? | | | |
| IVF/ICSI? | | | |
| Other treatment modalities? | | | |
| Do the schedules include details on dosage? | | | |
| Do the schedules include details on timing of all practical aspects? | | | |
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| **CONSENT FORMS** | | | |
| Do all concerned individuals sign a consent form before treatment? | | | |
| Is there a consent form concerning cryopreservation? | | | |
| Is there a consent form concerning embryo replacement after thawing? | | | |
| Is there a consent form concerning the use of spare embryos? | | | |
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| **CLINICAL ASSESSMENT** | | | |
| Is relevant clinical data collected and assessed before treatment? | | | |
| Is medical data collected concerning earlier infertility treatment? | | | |
| Is medical data collected concerning earlier Assisted Reproduction? | | | |
| Is the psycho-social situation a part of the clinical assessment? | | | |
| Does the program include the following routine tests: | | | |
| HIV 1 + 2 ? | | | |
| Hepatitis B antigen ? | | | |
| Hepatitis C? | | | |
| Rubella antibodies? Female only. | | | |
| Toxoplasmosis antibodies? Female only. | | | |
| Karyotyping before ICSI? Male only. | | | |
| Karyotyping before ICSI? Male- female. | | | |
| Y-chromosome deletions? Male only. | | | |
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| **PROGNOSIS AND TREATMENT PLANNING** | | | |
| Are treatment alternatives identified for the couple? | | | |
| Are arguments for the selected treatment documented in the records? | | | |
| Is there a written treatment schedule for each treatment cycle? | | | |
| Does the couple receive a copy of the treatment schedule? | | | |
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| **MONITORING OF OVARIAN STIMULATION** | | | |
| Is monitoring of ovarian stimulation done by ultrasound examination? | | | |
| Is there a ready access to estradiol measurement? | | | |
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| **OOCYTE RETRIEVAL** | | | |
| Is the procedure described in a manual? | | | |
| Is there adequate staff present at oocyte retrieval? | | | |
| Is there a nurse present? | | | |
| Is there a laboratory technician present? | | | |
| Is there ready access to emergency back-up? | | | |
| Is there a schedule for pain-relief under and after ovum pickup? | | | |
| Is there resuscitation equipment available for emergencies? | | | |
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| EMBRYO TRANSFER | | | |
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| Is the procedure described in a manual? | | | |
| Is there an individualised protocol for the Nr of embryos transferred? | | | |
| Are arguments for occasional three-embryo transfer documented? | | | |
| Is there a protocol for single embryo transfer? | | | |
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| **LABORATORY CHECKLIST:** | | | |
| **LABORATORY MANUAL** | | | |
| Is the manual reviewed regularly? | | | |
| Half yearly? | | | |
| Yearly? | | | |
| Are all changes in procedures approved by the laboratory director? | | | |
| Are laboratory personnel updated and trained on revised procedures? | | | |
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| **PROCEDURES** | | | |
| Are the following procedures described in the manual: | | | |
| Preparation of all culture media? | | | |
| Identification of oocytes? | | | |
| Assessment of oocyte quality? | | | |
| Sperm assessment? | | | |
| Sperm preparation for: | | | |
| AIH/AID? | | | |
| IVF? | | | |
| ICSI? | | | |
| MESA/TESE? | | | |
| Insemination of oocytes? | | | |
| Microinsemination of oocytes? | | | |
| Pronucleus assessment? | | | |
| Pre-embryo assessment? | | | |
| Pre-embryo selection? | | | |
| Pre-embryo transfer procedure? | | | |
| Cryopreservation of sperm? | | | |
| Cryopreservation of oocytes? | | | |
| Cryopreservation of pre-embryos? | | | |
| All micromanipulation procedures: | | | |
| ICSI? | | | |
| Assisted hatching? | | | |
| Polar body removal? | | | |
| Blastomere removal? | | | |
| Manufacture of pipettes? | | | |
| Genetics procedures (where applicable): | | | |
| FISH | | | |
| PCR | | | |
| In Vitro Maturation IVM | | | |
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| EQUIPMENT AND MATERIALS | | | |
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| Is there a list of all material used, including the source? | | | |
| Is there a list of all chemicals used, including the source? | | | |
| Is there a list of equipment? | | | |
| Is there a protocol on breakdown and repair of equipment? | | | |
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| **RECORD KEEPING** | | | |
| Is there a detailed procedure for keeping records? | | | |
| Does the record keeping procedure facilitate reporting of results? | | | |
| Are results regularly communicated within the laboratory? | | | |
| Weekly? | | | |
| Monthly? | | | |
| Quarterly? | | | |
| Are results regularly communicated to the clinical team? | | | |
| Weekly? | | | |
| Monthly? | | | |
| Quarterly? | | | |
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| **LABORATORY CLEANING** | | | |
| Is there a written protocol for cleaning laboratory rooms? | | | |
| Is there a written protocol for cleaning materials before use? | | | |
| Is there a written protocol for the handling of disposable waste? | | | |
| Is there a written protocol for the handling of biological material? | | | |
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| **EQUIPMENT** | | | |
| Is there a log book of maintenance for the following equipment: | | | |
| Incubators? | | | |
| Freezer? | | | |
| Micromanipulation equipment? | | | |
| Other laboratory equipment? | | | |
| Is there a list of equipment that regularly requires calibration? | | | |
| Is there a manual describing calibration of incubators? | | | |
| Incubator calibration is done: | | | |
| Daily? | | | |
| Weekly? | | | |
| Is there a protocol for incubator cleansing? | | | |
| Are manufacturers quality control guidelines available for: | | | |
| Incubators | | | |
| Freezers | | | |
| Other laboratory equipment? | | | |
| Cryostorage equipment: | | | |
| Is there a method to monitor and maintain liquid N2 levels? | | | |
| Alarm systems: | | | |
| Is there a 24-hour alarm facility for incubators surveillance? | | | |
| Is there a 24-hour alarm facility for all N2 cryo-storage tanks? | | | |
| Are thermometers used in incubators accredited? | | | |
| Is there an electrical back-up system for crucial equipment? | | | |
| Is there periodic (yearly) training in use of equipment? | | | |

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| **MONITORING OF RESULTS** | | | |
| Does current monitoring of results clearly allow calculation of: | | | |
| Average number of oocytes per follicle aspiration? | | | |
| The distribution of oocyte quality? | | | |
| Fertilization rate (2 pronuclear oocytes / inseminated oocytes)? | | | |
| Cleavage rate of pre-embryos in relation to days after insemination? | | | |
| Fertilized oocytes with 3 or more pronuclei? | | | |
| Distribution of pre-embryo quality? | | | |
| Developmental stage of pre-embryos replaced? | | | |
| Photographs of pre-embryos replaced? | | | |
| Implantation rate (implantations per pre-embryo replaced)? | | | |
| Spare embryos suitable for cryopreservation? | | | |
| Spare embryos selected for research? | | | |
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| **IDENTIFICATION AND LABELLING.** | | | |
| **PATIENT IDENTIFICATION:** | | | |
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| **IN THE CLINIC** | | | |
| Are all points of patient identification clearly described in the manual? | | | |
| Are photographs of couples used as part of the identification security? | | | |
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| **IN THE LABORATORY** | | | |
| Is there a written procedure on how to identify patients? | | | |
| Is it clearly stated how personnel connect specimen to patient/couple? | | | |
| Is it clearly stated how personnel identify oocytes and pre-embryos? | | | |
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| **LABELLING** | | | |
| Is there a written instruction on collection and handling of specimens? | | | |
| Is there a written procedure for labelling biological material: | | | |
| Blood? | | | |
| Serum? | | | |
| Semen? | | | |
| Sperm? | | | |
| Follicular fluid? | | | |
| Oocytes? | | | |
| Pre-embryos? | | | |
| Cryopreserved sperm? | | | |
| Cryopreserved oocytes? | | | |
| Cryopreserved pre-embryos? | | | |
| Donor sperm? | | | |
| Donor oocytes? | | | |
| Donor pre-embryos? | | | |
| Is it defined how sperm samples are labelled: male only, or couple? | | | |
| Is it defined how cryostraws/ampules are labelled? Female, or couple? | | | |
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| ERRORS | | | |
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| Is the transfer catheter checked for remaining pre-embryos? | | | |
| Is there a policy of action in case of errors at pre-embryo transfer? | | | |
| Is there a policy on errors in labelling? | | | |
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| **LOG BOOK** | | | |
| Is there a clinical and laboratory log book that records: | | | |
| The personnel on duty each day? | | | |
| Activities undertaken each day? | | | |
| Deviations from the manual? | | | |
| Extraordinary measures? | | | |
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| **FACILITIES** | | | |
| Is there an architectural plan available of the facility? | | | |
| Is the operating room and embryo laboratory in close proximity? | | | |
| Does the laboratory facilitate aseptic handling of gametes and embryos? | | | |
| Is there separate office space provided for laboratory administration? | | | |
| Is there a location for disinfection and sterilisation? | | | |
| Are cleaning and sterilisation facilities separate from the embryo lab? | | | |
| Is there adequate space for secure sperm preparation? | | | |
| Is there adequate ventilation? | | | |
| Is there a suitable working climate/temperature in the embryo lab? | | | |
| Are there adequate lighting facilities? | | | |
| Is there a suitable facility for production of semen samples? | | | |
| Are there convenient lavatory facilities? | | | |
| Is there an adequate system for waste disposal in the lab? | | | |
| Are gas cylinders placed in accordance with regulations? | | | |
| Are there adequate fire escape routes? | | | |
| Are regulations for visitors documented? | | | |
| Is there a list of personnel that have access to the clinic and laboratory? | | | |
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| **Quality assurance in the laboratory:** | | | |
| **PROTECTION of clinical and laboratory staff** | | | |
| Are there written policies on the following: | | | |
| Protection of staff against transmittable diseases? | | | |
| Protection of staff against toxic chemicals? | | | |
| The use of laboratory clothing? | | | |
| The use of gloves and masks? | | | |
| The use of safety goggles and safety gloves? | | | |
| Shoes, and shoe covers? | | | |
| Scrubs and gowns? | | | |
| Use of laminary flow benches? | | | |
| Use of mechanical or manual pipetting devices? | | | |
| Vaccinations: | | | |
| Is staff offered vaccination against Hepatitis B? | | | |
| Are treatment couples screened for: | | | |
| HIV? | | | |

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| Hepatitis B | | | |
| Hepatitis C | | | |
| Other sexually transmitted diseases? | | | |
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| **Clinical and laboratory:** | | | |
| **DOCUMENTATION OF RESULTS** | | | |
| Does documentation ensure couple privacy? | | | |
| Are the following data documented for IVF, ICSI, MESA, TESE: | | | |
| Nr of couples treated? | | | |
| Nr of started cycles? | | | |
| Nr of cancelled cycles? | | | |
| Nr of oocyte retrievals? | | | |
| Nr of transfer cycles? | | | |
| Nr of cryopreservations of sperm, oocytes and pre-embryos? | | | |
| Nr of embryo thawing cycles, FER. | | | |
| Nr of oocyte donation cycles? | | | |
| Nr of IVF sperm donation cycles? | | | |
| Nr of Embryodonation cycles? | | | |
| Nr of AID cycles? | | | |
| Nr of surrogacy cycles? | | | |
| The distribution of: | | | |
| singletons, twins and high order multiple pregnancies? | | | |
| Ectopic pregnancies, spontaneous and therapeutic abortions? | | | |
| Embryo reductions? | | | |
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| Are the total number of pre-embryos transferred documented? | | | |
| Is the average number of embryos transferred documented? | | | |
| Are the number of births documented: | | | |
| Per started cycle? | | | |
| Per oocyte retrieval? | | | |
| Per transfer? | | | |
| | | | |
| Are the number of births per embryo transferred documented? | | | |
| Are outcomes presented according to the age of the woman? | | | |
| Are outcomes presented according to the treatment indication? | | | |
| Are the following documented about births: | | | |
| Birth weights? | | | |
| Average birth weight for singletons? | | | |
| Average birth weight for twins? | | | |
| Average birth weight for triplets? | | | |
| Average birth weight for quads? | | | |
| Gestational length at delivery? | | | |
| For singletons? | | | |
| Twins? | | | |
| Triplets? | | | |
| Quads? | | | |
| Are malformations documented? | | | |
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| Are the following side effects and complications documented: | | | |

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|---|---|---|---|
| Allergic reactions? | | | |
| Intra-abdominal bleeding? | | | |
| Infection? | | | |
| OHSS (Ovarian hyperstimulation syndrome)? | | | |
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| Is an annual report available containing the data outlined above? | | | |
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| **RESPONSIBILITY** | | | |
| Is the chain of responsibility for clinical activities written down? | | | |
| Is the chain of responsibility for laboratory activities written down? | | | |
| Are the following clearly indicated: | | | |
| Available staff during normal and odd-working hours? | | | |
| Persons authorized to make changes to manuals? | | | |
| Is the required competence needed for given procedures clearly stated? | | | |
| | | | |
| **QUALITY CONTROL** | | | |
| Is there a quality control program? | | | |
| Are batch numbers registered for | | | |
| Drugs? | | | |
| Culture media? | | | |
| Transfer catheters? | | | |
| Other disposables? | | | |
| Is there a documented procedure for the buying of materials? | | | |
| Are quality requirements documented for all bought articles? | | | |
| Is there a list of suppliers? | | | |
| Are industrial complaints registered? | | | |
| Is the clinic subject to internal audit? | | | |
| Is the clinic subject to external audit? | | | |
| | | | |
| **QUALITY ASSURANCE** | | | |
| Are there regular meetings for clinical and laboratory staff to review: | | | |
| Results? | | | |
| Complications? | | | |
| Are annual reports on results available? | | | |
| Is there documentation of clinical problems? | | | |
| Is there documentation of laboratory problems? | | | |
| Is there documentation of corrective action for data out of tolerance range? | | | |
| Are the following clearly detailed: | | | |
| Path of action for all warning systems: | | | |
| Medical emergencies? | | | |
| Electrical failure? | | | |
| Incubator alarms? | | | |
| N2 level alarms? | | | |
| Are couple/patient complaints registered? | | | |
| Are studies done on couple/patient satisfaction? | | | |
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| STAFF | | | |
|---|---|---|---|
| Is there evidence of continuing education for clinical staff? | | | |
| Is there evidence of continuing education for laboratory staff? | | | |
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| **Legal and ethical issues** | | | |
| Is all the staff updated on national regulations concerning ART? | | | |
| Are there regularly held meetings to discuss ethical issues: | | | |
| Half yearly? | | | |
| Yearly? | | | |
| Is the staff informed of privacy and secrecy regulations? | | | |

Edited by J.T.Hazekamp 2002, for the NFS board.

References:
1.Clinical and laboratory guidelines for assisted reproductive technologies in the Nordic countries. NFOG supplement nr 3.97.
2.1993 Inspection checklist. Reproductive laboratory Accreditation Program. College of American Pathologists.
3.Quality handbook for clinical embryology 1996. Netherlands society for clinical embryologists.