



QA in transport PGD

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transport PGD

ESHRE PGD consortium



transport PGD - how?



transport PGD

1 (licensed) centre for genetic diagnosis
multiple IVF centers



transport PGD – why?



transport PGD

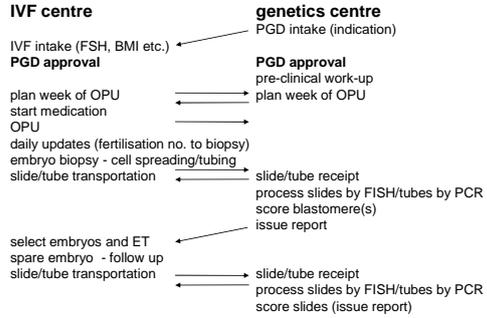
efficient use resources
concentrate know-how
facilitate access for patients

- ensure highest quality





transport PGD – key events





transport PGD

continuous transfer of information and materials

- regulatory requirements
- terms & conditions
- documentation



regulatory requirements

- EU directives (reproduction / genetics)
- national law (IVF / PGD license)
- laboratory accreditation (IVF / genetics)
- contracts (collaboration)
- insurance
- refunding



terms & conditions

- site visit
(equipment, consumables, spreading/tubing procedures)
- training sessions
(genetic counseling, biopsy, spreading, tubing, interpretation results)
- contact/communication (incl. back-up)
- transport service
- timetable
- test run
- evaluation

QMS and accreditation in PGD clinics and laboratories, October 23 2008



documentation

- made available to either transport partner
- joint protocols authorized by either transport partner
- controlled version
- strict compliance
- 'double checks'

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documentation - SOPs

- joint PGD transport protocol (clinical, laboratory) responsibility
- PGD – biopsy protocol
- PGD – blastomere spreading protocol
- PGD – blastomere tubing protocol
- PGD – FISH X-linked protocol
- PGD – FISH translocation protocol
- PGS protocol
- PGD – PCR disease specific protocol

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documentation - forms

- logistics (who, what, where, when)
- biopsy
- blastomere spreading / tubing
- raw FISH / PCR data

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documentation - reports

- PGD - FISH results
- PGD - PCR results
- PGS results
- embryo follow-up (quality control)

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report - example

Enclosure PGD-FISH analysis

page 1/1

name: Mrs. J-B		indication : translocation		OPU date:		
date: xx-xx-xxxx		genotype: 46,XY,t(12;13)		no. Oo:		
PGD no: XXXX.1				ICSI/no. MI:		
hospital:				no. embryos biopsied:		
embryo	fertilization	embryo biopsy	biopsy / spreading details	genotype	phenotype	transferable
A1	2 PN	8C / 2	bl. A1.1 no remarks bl. A1.2 binucleate		unbalanced	no
A2	2 PN	7C / 3	bl. A2.1 no remarks		unbalanced	no
B1	0 PN	5C / 2-3	b1.1 additional fragments		not conclusive	no
B2	2 PN	8C / 2	b2.1 no remarks b2.2 no remarks		normal / balanced	yes
signature	IVF	IVF	IVF	genetics	genetics	genetics

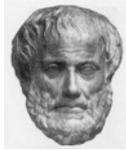
Authorization

Date	Name	Signature
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'Quality is no stage, It is a habit'

Aristoteles (384vC-322vC); Greek philosopher and scientist



QMS and accreditation in PGD clinics and laboratories, October 23 2008
