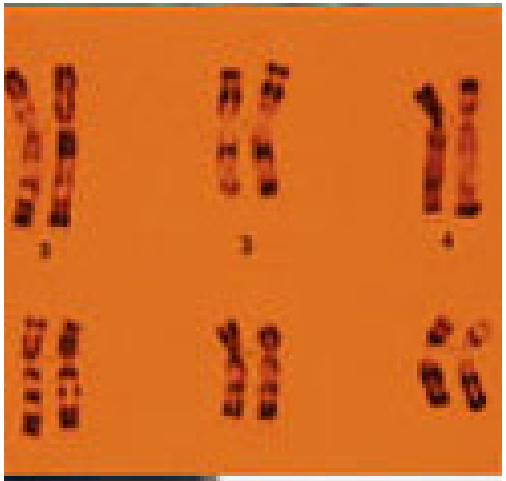

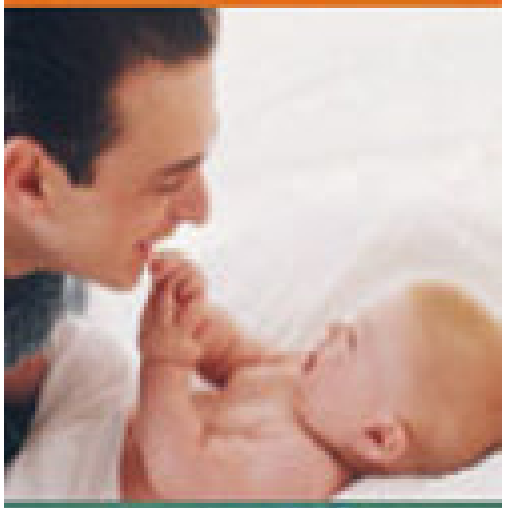

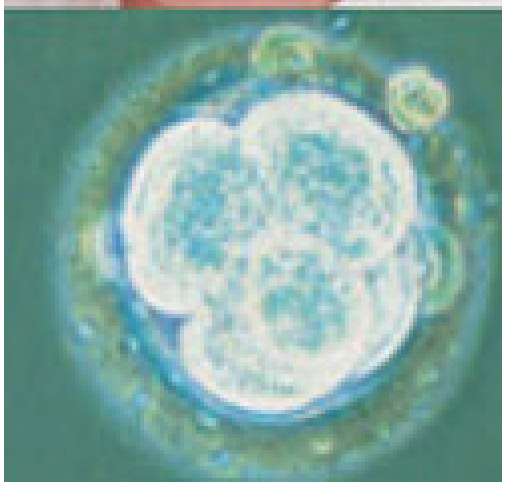

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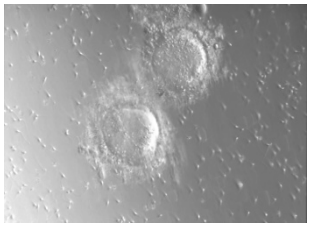
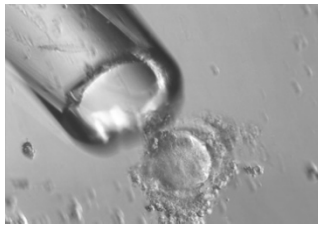
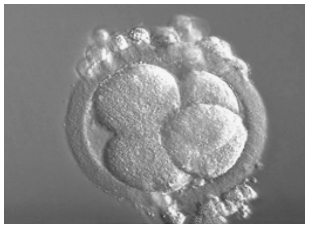






New European Union Directives and their implications on art

D Royere, Reproductive Medecine and Biology, UMR6175 INRA/CNRS/Haras nationaux/Université F Rabelais, CHRU de Tours, France

European Union Tissues and Cells Directives

- **Which are the directives with a special emphasis on ART concerns**
- European Assisted Conception Consortium
- Common approach for definition of SAR, SAE
- Eshre Clinical Embryology certification scheme
- Eshre guidelines for good laboratory practice

European Union Tissues and Cells Directives

- "Mother" Directive 2004/23/EC of 31/03/2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells
  - To be transposed no later than 7/04/2006

European Union Tissues and Cells Directives

- "Technical" directive 2006/17/EC of 8/02/2006 implementing the previous one as regards certain technical requirements for the donation, procurement, and testing of human tissues and cells
  - To be transposed no later than 1/11/2006
- "Technical" directive 2006/86/EC of 24/10/2006 implementing the "mother" directive as regards traceability requirements, notification of serious adverses reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells
  - To be transposed no later than 1/09/2007

European Union Tissues and Cells Directives 2004/23/EC

There is an urgent need for a unified framework in order to ensure high standards of quality and safety with respect to the procurement, testing, processing, storage and distribution of tissues and cells across the Community and to facilitate exchanges thereof for patients receiving this type of therapy each year. It is essential, therefore, that Community provisions ensure that human tissues and cells, whatever their intended use, are of comparable quality and safety. The establishment of such standards, therefore, will help to reassure the public that human tissues and cells that are procured in another Member State, nonetheless carry the same guarantees as those in their own country.

Objective

This Directive lays down standards of quality and safety for human tissues and cells intended for human applications, in order to ensure a high level of protection of human health.

Commission européenne

1. Member States shall ensure that tissue and cell procurement and testing are carried out by persons with appropriate training and experience and that they take place in conditions accredited, designated, authorised or licensed for that purpose by the competent authority or authorities.

Inspections and control measures

3. Inspections shall be organised and control measures shall be carried out by the competent authority or authorities on a regular basis. The interval between two inspections shall not exceed two years.

5. Guidelines concerning the conditions of the inspections and control measures, and on the training and qualification of the officials involved in order to reach a consistent level of competence and performance, shall be established in accordance with the procedure referred to in Article 29(2).

European Union Tissues and Cells Directives 2004/23/EC

Traceability

2. Member States shall ensure the implementation of a donor identification system which assigns a unique code to each donation and to each of the products associated with it.

Import/export of human tissues and cells

(c) The competent authority or authorities shall take all necessary measures to ensure that imports and exports of tissues and cells referred to in subparagraphs (a) and (b) meet quality and safety standards equivalent to those laid down in this Directive.

Notification of serious adverse events and reactions

Commission européenne

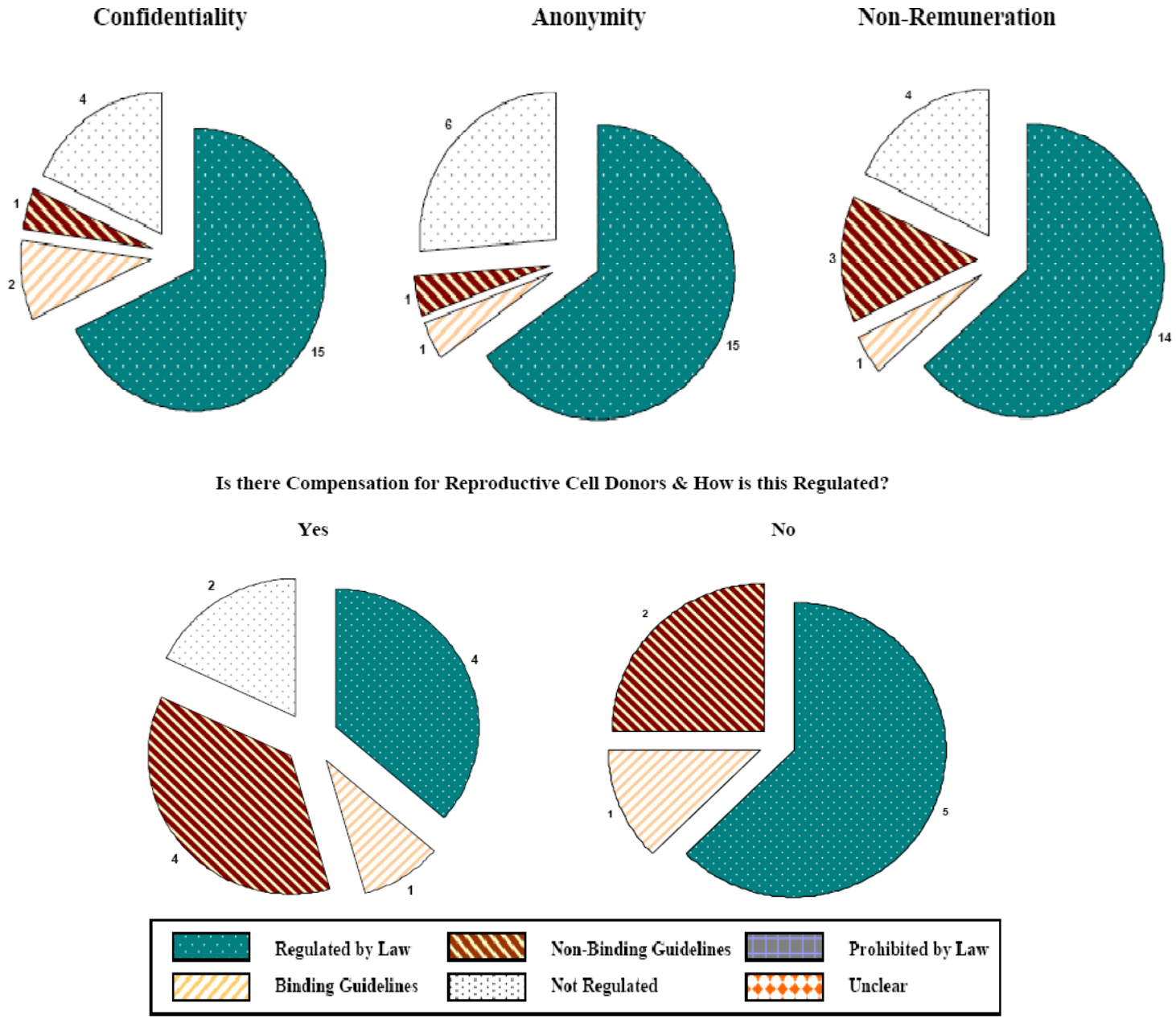
Principles governing tissue and cell donation

1. Member States shall endeavour to ensure voluntary and unpaid donations of tissues and cells.

Donors may receive compensation, which is strictly limited to making good the expenses and inconveniences related to the donation. In that case, Member States define the conditions under which compensation may be granted.

Data protection and confidentiality

3. Member States shall take all necessary measures to ensure that the identity of the recipient(s) is not disclosed to the donor or his family and vice versa, without prejudice to legislation in force in Member States on the conditions for disclosure, notably in the case of gametes donation.



http://ec.europa.eu/health/ph_threats/human_substance/keydo_tissues_cells_en.htm

European Union Tissues and Cells Directives 2004/23/EC

Quality management

3. Tissue establishments shall take all necessary measures to ensure that the quality system includes at least the following documentation:

— standard operating procedures,

— guidelines,

— training and reference manuals,

— reporting forms,

— donor records,

— information on the final destination of tissues or cells.

Responsible person

Personnel

Personnel directly involved in activities relating to the procurement, processing, preservation, storage and distribution of tissues and cells in a tissue establishment shall be qualified to perform such tasks and shall be provided with the training referred to in Article 28(c).

Technical requirements and their adaptation to scientific and technical progress

The following technical requirements and their adaptation to scientific and technical progress shall be decided in accordance with the procedure referred to in Article 29(2):

(a) requirements for the accreditation, designation, authorisation or licensing of tissue establishments;

(b) requirements for the procurement of human tissues and cells;

(c) quality system, including training;

(d) selection criteria for the donor of tissues and/or cells;

(e) laboratory tests required for donors;

(f) cell and/or tissue procurement procedures and reception at the tissue establishment;

(g) requirements for the tissue and cell preparation process;

(h) tissue and cell processing, storage and distribution;

(i) requirements for the direct distribution to the recipient of specific tissues and cells.

European Union Tissues and Cells Directives 2006/86/EC

(5) The air quality standard during the processing of tissues and cells is a key factor that may influence the risk of tissue or cell contamination. An air quality with particle counts and microbial colony counts equivalent to those of Grade A, as defined in the European Guide to Good Manufacturing Practice, Annex 1 and Commission Directive 2003/94/EC (2), is generally required. However, in certain situations, an air quality with particle counts and microbial colony counts equivalent to those of Grade A standard is not indicated. In these circumstances it should be demonstrated and documented that the chosen environment achieves the quality and safety required for the type of tissue and cells, process and human application concerned.

(6) The scope of this Directive should embrace the quality and safety of human tissues and cells during coding, processing, preservation, storage and distribution to the healthcare establishment where they will be applied to the human body. However, it should not extend to the human application of these tissues and cells (such as implantation surgery, perfusion, insemination or transfer of embryos). The provisions of this Directive

Notification of serious adverse events

2. In the case of assisted reproduction, any type of gamete or embryo misidentification or mix-up shall be considered to be a serious adverse event. All persons or procurement organisations or organisations responsible for human application performing assisted reproduction shall report such events to the supplying tissue establishments for investigation and notification to the competent authority.

Commission européenne

European Union Tissues and Cells Directives

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European Union Tissues and Cells Directives 2006/17/EC

Reproductive cells have, due to the specific nature of their application, specific quality and safety characteristics that are taken into account in this Directive.

(a) 'reproductive cells' means all tissues and cells intended to be used for the purpose of assisted reproduction;

(b) 'partner donation' means the donation of reproductive cells between a man and a woman who declare that they have an intimate physical relationship;

(c) 'direct use' means any procedure where cells are donated and used without any banking;

5. There shall be standard operating procedures (SOPs) for the verification of:

(a) donor identity;

(b) the details of donor or donor family consent or authorisation;

(c) the assessment of the selection criteria for donors as detailed in Article 3;

(d) the assessment of the laboratory tests required for donors as detailed in Article 4.

Commission européenne

European Union Tissues and Cells Directives 2006/17/EC

SELECTION CRITERIA AND LABORATORY TESTS REQUIRED FOR DONORS OF REPRODUCTIVE CELLS AS REFERRED TO IN ARTICLE 3(b) AND ARTICLE 4(2)

1. Partner donation for direct use

Donor selection criteria and laboratory testing do not need to be applied in the case of partner donation of reproductive cells for direct use.

2. Partner donation (not direct use)

Reproductive cells that are processed and/or stored and reproductive cells that will result in the cryopreservation of embryos must meet the following criteria:

2.1. the clinician responsible for the donor must determine and document, based on the patient's medical history and therapeutic indications, the justification for the donation and its safety for the recipient and any child(ren) that might result;

2.2. the following biological tests must be carried out to assess the risk of cross-contamination:

HIV 1 and 2	Anti-HIV-1,2
Hepatitis B	HBsAg Anti-HBc
Hepatitis C	Anti-HCV-Ab

In case of sperm processed for intrauterine insemination and not to be stored, if the tissue establishment can demonstrate that the risk of cross contamination and staff exposure has been addressed through the use of validated processes, biological testing may not be required;

2.3. where HIV 1 and 2, hepatitis B or hepatitis C test results are positive or unavailable, or where the donor is known to be a source of infection risk, a system of separate storage must be devised;

2.4. HTLV-I antibody testing must be performed for donors living in or originating from high-incidence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas;

2.5. in certain circumstances, additional testing may be required depending on the donor's travel and exposure history and the characteristics of the tissue or cells donated (e.g. Rh D, malaria, CMV, *T. cruzi*);

2.6. positive results will not necessarily prevent partner donation in accordance with national rules.

1. Donations other than by partners

The use of reproductive cells other than for partner donation must meet the following criteria:

1.1. donors must be selected on the basis of their age, health and medical history, provided on a questionnaire and through a personal interview performed by a qualified and trained healthcare professional. This assessment must include relevant factors that may assist in identifying and screening out persons whose donation could present a health risk to others, such as the possibility of transmitting diseases (such as sexually transmitted infections), or health risks to themselves (e.g. superovulation, sedation or the risks associated with the egg collection procedure or the psychological consequences of being a donor);

1.2. the donors must be negative for HIV 1 and 2, HCV, HBV and syphilis on a serum or plasma sample, tested in accordance with Annex II, point 3.1, and sperm donors must additionally be negative for chlamydia on a urine sample tested by the nucleic acid amplification technique (NAT);

1.3. HTLV-I antibody testing must be performed for donors living in or originating from high-incidence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas;

3.4. in certain circumstances, additional testing may be required depending on the donor's history and the characteristics of the tissue or cells donated (e.g. RhD, malaria, CMV, *T. cruzi*).

3.5. for autologous donors, Annex I, point 2.1.1 applies;

3.6. genetic screening for autosomal recessive genes known to be prevalent, according to international scientific evidence, in the donor's ethnic background and an assessment of the risk of transmission of inherited conditions known to be present in the family must be carried out, after consent is obtained. Complete information must be provided, in accordance with the requirements in force in Member States. Complete information on the associated risk and on the measures undertaken for its mitigation must be communicated and clearly explained to the recipient.

4. General requirements to be met for determining biological markers

4.1. The tests must be carried out in accordance with Annex II, points 2.1 and 2.2.

4.2. Blood samples must be obtained at the time of donation.

4.3. Sperm donations other than by partners will be quarantined for a minimum of 180 days, after which repeat testing is required. If the blood donation sample is additionally tested by the nucleic acid amplification technique (NAT) for HIV, HBV and HCV, testing of a repeat blood sample is not required. Retesting is also not required if the processing includes an inactivation step that has been validated for the viruses concerned.

European Union Tissues and Cells Directives

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European Assisted Conception Consortium 2005/06/20

- To understand all implications of the EUTCD
- To identify areas problematic to the ART community
- To provide interpretations to be used locally in all the European countries
- To facilitate a dialog between EU, the profession and the national regulative authorities
- To act as a communication channel to the European Commission
- Each EU member state to be represented by one clinician, one biologist and one representative of the competent authority (ies)

European Assisted Conception Consortium 2005/06/20

The European Assisted Conception Consortium (EACC) is an initiative supported by the European Society of Human Reproduction and Embryology (ESHRE)

First Committee : ***Chair:*** ***Angela McNab (UK, regulator)***

Executive members: ***Bernard Loty (France, regulator)***

Anna Veiga (Spain, embryologist)

Josiane Van der Elst (Belgium,embryologist)

Ioannis Messinis (Greece, clinician)

European Assisted Conception Consortium 2005/06/20

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Chair:	***Josiane Van der Elst (Belgium,embryologist)***
Executive members:	***Bernard Loty (France, regulator)***
	Anna Veiga (Spain, embryologist)
	Basil Tarlatzis (Greece, regulator)
	Ioannis Messinis (Greece, clinician)
	Cristina Magli (Italy, embryologist)
	Edgar Mocanu (Ireland, embryologist)

Eshre position paper 2007/11 on the EU TCD EC/2004/23

- EUTCD have to be interpreted and implemented through national authorities in each country
- National implementation is subject to national regulations that may be already in place in each member state
- All units have to be licensed or accredited as decided by the national authorities
- Quality management system, doc kept for 30 years
- Management of viral positive patients to be clearly defined by national authorities

Eshre position paper on the EU TCD EC/2004/23

EUTCD that are clearly defined

- The directive applies to fresh and cryopreserved reproductive tissues and cells for application to the human body. This covers gametes, zygotes, embryos and ovarian and testicular tissues.
- The directive is concerned with issues of safety and quality in ART such as prevention of transmission of infectious disease and prevention of misidentification or mix-up of gametes, zygotes or embryos. Each tissue establishment has to put in place and update a quality management system based on the principles of good practice.
- The directive applies to all ART procedures where reproductive cells and tissues are being processed, cultured, banked or stored. This means that intra-uterine insemination falls under the EUTCD. The terminology "direct use" is not applicable on reproductive tissues and cells that will be processed, cultured, banked or stored.
- "Donor" means every human source, whether living or deceased, of human cells and tissues. Partner donation means the donation of reproductive cells between a man and a woman who declare to have an intimate physical relationship. In a couple, man and woman are considered donors to each other.

Eshre position paper on the EU TCD EC/2004/23

- Biological testing of the donor is necessary whenever the donated cells will be processed, cultured, banked or stored. Biological testing for HIV 1, 2, for Hepatitis B surface Antigen, Hepatitis B Core antibodies and Hepatitis C antibodies is requested.
- For non-partner donation, additional screening for syphilis and in case of sperm donation for Chlamydia is required.
- Genetic screening for recessive diseases known to be prevalent in a non- partner donors' ethnic background is requested.
- Cells and tissues have to be traceable from donor to acceptor and vice versa. Traceability is also mandatory to all products and materials coming into contact with tissues and cells. This includes for instance all culture media, all culture media supplements and all disposables,
- A unique European coding system is not applicable to reproductive tissues and cells for partner donation. A unique code guaranteeing traceability remains however required.
- The EU has ordered a workshop at CEN, the European Committee of Standardization, to propose a unique European coding system which will apply in case of non -partner donation.
- In assisted reproduction every misidentification or mix-up of gametes, zygotes or embryos is to be considered a serious adverse event.

European Union Tissues and Cells Directives

- Which are the directives with a special emphasis on ART concerns
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EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Public Health and Risk Assessment
Health Law and International

Brussels, 25 July 2009
SANCO C6 PL/hp D(2009) 360242

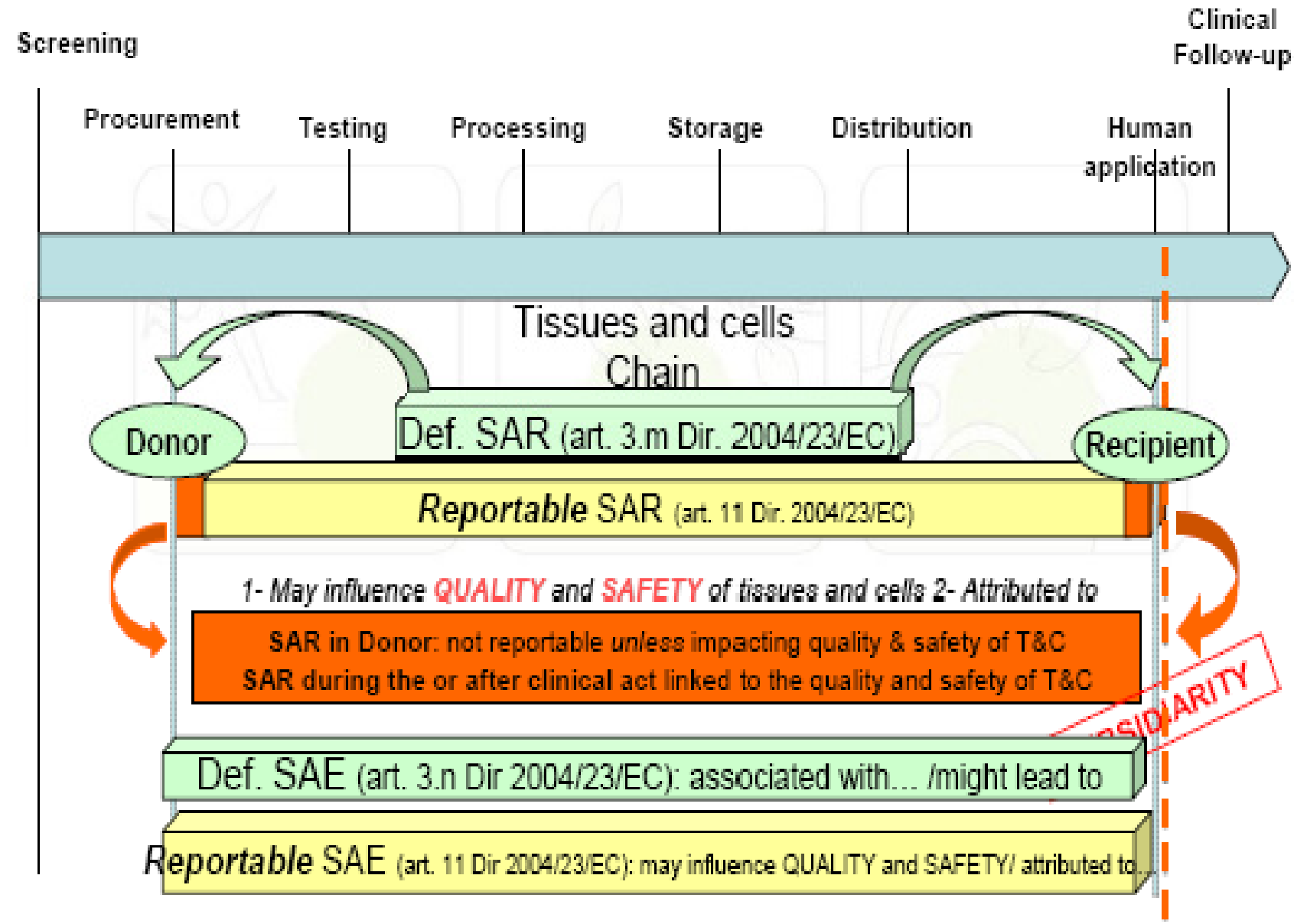
COMMON APPROACH FOR DEFINITION OF REPORTABLE SERIOUS ADVERSE EVENTS AND REACTIONS AS LAID DOWN IN THE TISSUES AND CELLS DIRECTIVE 2004/23/EC AND COMMISSION DIRECTIVE 2006/86/EC

VERSION 1.0 (2009)

COMMON APPROACH
FOR DEFINITION OF REPORTABLE SERIOUS ADVERSE EVENTS AND REACTIONS AS LAID DOWN IN THE TISSUES AND CELLS DIRECTIVE 2004/23/EC AND COMMISSION DIRECTIVE 2006/86/EC

VERSION 1.0 (2009)

According to Article 152 of the EC Treaty in relation to health care, the management of healthcare (i.e. clinical use of tissues and cells) is not a competence of the European Union and remains under the responsibility of the Member States. Thus adverse events occurring in the clinical context, such as surgical error during the implantation of tissues or cells, are not subject to mandatory reporting under the Tissues and Cells Directives. In a similar way, serious adverse reactions proven not to be attributable to the quality and safety of the tissues or cells (e.g. infection due to a contaminated surgical instrument during tissue implantation) are not subject to mandatory reporting under the Tissues and Cells Directive.


Screening
Clinical Follow-up
Procurement
Testing
Processing
Storage
Distribution
Human application
Tissues and cells Chain
Donor
Def. SAR (art. 3.m Dir. 2004/23/EC)
Recipient
Reportable SAR (art. 11 Dir. 2004/23/EC)
1- May influence QUALITY and SAFETY of tissues and cells 2- Attributed to
SAR in Donor: not reportable unless impacting quality & safety of T&C
SAR during the or after clinical act linked to the quality and safety of T&C
Def. SAE (art. 3.n Dir 2004/23/EC): associated with… /might lead to
Reportable SAE (art. 11 Dir 2004/23/EC): may influence QUALITY and SAFETY/ attributed to…

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VERSION 1.0 (2009)

1.1.2. Which organizations should report SAR/E to the competent authority in a Member State? Articles 5 and 6 of Directive 2006/86/EC specify that 'procurement organisations', 'organisations responsible for human application' and 'tissue establishments' have responsibilities to report SAR/E. In general, procurement organizations and organizations responsible for human application should report to the TE which receives or supplies the tissue and cells concerned. The TE is responsible for reporting to the competent authority. The CA should also accept SAR/E direct from procurement organizations or organizations responsible for human application (see recital (9) of Directive 2006/86/EC).

Reproductive Tissues and Cells:
Sperm
Oocyte
Embryo*
Other Reproductive tissues and cells (e.g. ovarian or testicular tissue)

2.5. Nature of Serious Adverse Reaction(s) reported

2.5.1. The annual report template as previously drafted included 5 categories of disease transmission (bacterial infections, viral infections, parasitic infections, malignant disease and other disease transmission). Prion, immunological and genetic disease transmissions could be included in the 'other disease transmission' category. The following category has been added: "Other Adverse Reactions" to allow the reporting of serious adverse reactions that do not involve a disease transmission, e.g. structural graft failure, toxicity, allergic reactions or unnecessary repeat surgery due to the provision of an incorrect or unsuitable tissue or cells, that would fall under the definition of SAR in the Directive.

influencing the quality and safety of tissues and cells. Reactions such as Ovarian Hyper-Stimulation Syndrome (OHSS) and reactions to Granulocyte Colony-Stimulating Factor (GCSF) following peripheral blood stem cell collection, or reactions which result in harm to the donor i.e. cardiac or neurological episode might impact on the willingness of donors to donate and therefore on the supply for patients needing treatment. In general, these reactions fall outside the scope of the tissues and cells Directives and should be reported to pharmacovigilance systems where appropriate. The Commission recognizes the value of this data, in the context of tissue and cells regulation, and invites Member States to submit an annual report concerning donor reactions reported to the CA on a voluntary basis (see 1. Scope, above). An additional non-mandatory category on donor reactions

2.6.3. It should be understood that, as stated in Article 6(2) of Directive 2006/86/EC, 'in the case of assisted reproduction, any type of gamete or embryo misidentification or mix-up shall be considered as a serious adverse event.' Therefore, even if such an event causes serious psychological damage, it should not be reported as a serious adverse reaction. However, if a SAR occurred as a result of gamete or embryo misidentification i.e. disease transmission, then it should be reported as a reaction.

3. Guidance on Reportable Serious Adverse Events

The electronic report template includes terms which are taken from Annex V, part B of Directive 2006/86/EC (Annual notification for serious adverse events). The following definitions/interpretations are proposed to ensure a common approach to reporting this data.

3.3. Specification of SAEs:

3.3.1. The following categories are provided in Annex V, part B of Directive 2006/86/EC and in the electronic annual report template.

Tissues and cells defect (specify): this should be understood as a defect in the quality or safety of the tissues and cells due to an inherent unpredictable safety or quality deficit, e.g a defect due to an undiagnosed illness or genetic factor or an unknown exposure to a toxic agent.

Equipment failure (specify): this should be understood as a defect in the quality or safety of the tissues or cells due to a fault in critical equipment used in procurement, processing, storage or distribution.

Human error (specify): this should be understood as a defect in the quality or safety of the tissues or cells due to an error by a member of personnel during procurement, processing, storage or distribution.

Other: this should be understood as a defect in the quality or safety of the tissues or cells due to any other cause during procurement, processing, storage or distribution.

European Union Tissues and Cells Directives

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Eshre position paper on the EU TCD EC/2004/23

european society of human reproduction & embryology

Problematic areas with respect to the EUTCD

Frequency of screening for HIV and Hepatitis: (Commission Directive 2006/17/EC, Annex III.4.2.)

It is specified in the directive that all donors (patients) shall be tested for HIV and Hepatitis B and C at the "time of donation". It is however not specified if it is required to re-test the patient prior to each treatment or whether a specified interval will be acceptable. This will have a profound impact on the financial consequences of the directive.

For example, the EUTCD has been fully implemented in Denmark. The position of the Danish authorities is that screening for HIV and Hepatitis must be done "prior" egg-recovery and the test is valid for 24 month if the patients are tested negative. For egg donors the Danish authorities have specified that the test must be done no more than 30 days prior to donation. Based on the fact that assisted reproduction often is comprised of a "series of treatments" and that treatment is initiated based on a known status of infection of the couples ESHRE suggests a system were the patients in case of partner donation must be tested no more than 30 days prior to starting the initial treatment and if the test is negative the result should be valid for at least 24 months. If the test is definitely positive the couples are considered positive in all future treatments. All additional testing should only be done as a requirement for treating viral positive couples with ART.

Eshre position paper on the EU TCD EC/2004/23

Air quality: (Commission Directive 2006/86/EC, Annex I.D. Facilities/Premises)

It is stated that the air quality should be a GMP defined Grade A on a background air quality of Grade D unless a less stringent air quality may be justified according to one or more of the provisions set out under section 4. After having performed Assisted Reproduction in Europe for more than 20 years there is no documented evidence of a single case of transmission of infective diseases (hepatitis/HIV etc) that can be attributed to air quality in the laboratory. Further, with the introduction of screening of the patients prior to start of treatment as specified in the EUTCD, we will know the viral status of the patients we treat, enabling us to handle infectious patients in a separate environment from non-infectious patients.

On this background ESHRE considers assisted reproduction to be covered by section 4 and - with reference to historical documentation - that it has been both demonstrated and documented that the chosen environment achieves the quality and safety required for the intended purpose.

Eshre position paper on the EU TCD EC/2004/23

Coverage

ESHRE interprets the directive to cover ART "from needle to catheter". This means that procedures outside of this are not covered by the directive. Consequently, it is our opinion that well known side effects to the treatment such as OHSS are considered outside of the scope of the directive. However, although the EUTCD is mainly concerned with the laboratory it also covers clinical procedures involving procurement of reproductive cells such as oocyte aspiration.

Intra uterine insemination:

IUI is included in the directive as it involves processing of gametes and this may have a profound impact on insemination performed outside of regular fertility clinics/units.

Cost

There is no doubt that the implementation of the directive will be extremely expensive for the involved clinics/units and that increased financial support will be mandatory both in the public system and private clinics. Without such a financial support, an increase in cost to patients is to be expected, particularly at private clinics/units.

Eshre position paper on the EU TCD EC/2004/23

Personnel: (Commission Directive 2006/86/EC Annex I. B .Personnel)

It is stated in the directive that a) staff should be available in sufficient numbers, b) a training program should be available and c) that work descriptions must be clearly documented.

While recognizing these needs ESHRE wishes to specify that the number and the complexity of the treatments can vary profoundly between clinics/units. On this background ESHRE considers it impossible to define a general statement covering all type of clinics/units; staff requirements should be specified at each individual clinic/unit and the number and type of treatments offered. As a consequence of the EUTCD a new ESHRE initiative is the establishment of a certification system for clinical and senior clinical embryologists. The system aims at certifying both practical and theoretical competence of the laboratory staff.

European Union Tissues and Cells Directives

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Certification for clinical embryologists

Steering Group

Kersti Lundin (SE) (Coordinator)
Kay Elder (UK)
Borut Kovacic (SI)
Cristina Magli (IT) (Coordinator Special Interest Group Embryology)
Carlos Plancha (PT)
Heidi Roijemans (BE) (ESHRE Office)
Etienne van den Abbeel (BE)
Francesca Vidal (ES)

The exam in Barcelona 2008 (Seniors)

- Number of applications 170
- Number of accepted 154
- Number of examinations 148
- Number of successful examinations 121 (82%)

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SCIENCE MOVING PEOPLE MOVING SCIENCE

The exam in Amsterdam 2009 (Seniors and Clinicals)

- Number of accepted applications 215
- Number of examinations 188 (100 Seniors, 88 Clinicals)
- Number of successful examinations 116 (40 Seniors, 76 Clinicals)

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In summary…….

- Now 562 ESHRE certified Embryologists

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PEOPLE
MOVING SCIENCE

Rome 2010

- Exams for ”Senior Clinical” and ”Clinical”
- **Saturday** 26th June
- Application date; from October 15th to December 15th
- Must be ESHRE member *before* applying!

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SCIENCE MOVING PEOPLE MOVING SCIENCE

European Union Tissues and Cells Directives

- Which are the directives with a special emphasis on ART concerns
- European Assisted Conception Consortium
- Common approach for definition of SAR, SAE
- Eshre Clinical Embryology certification scheme
- **Eshre guidelines for good laboratory practice**

Guidelines for good practice in IVF laboratories

Human Reproduction Vol.23, No.6 pp. 1253–1262, 2008
Advance Access publication on March 29, 2008
doi:10.1093/humrep/den068

ESHRE Pages

Revised guidelines for good practice in IVF laboratories

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Guidelines for good practice in IVF laboratories

- Staffing and direction
- Policies and procedures
- Laboratory safety
  - Laboratory design
  - Laboratory equipment
  - Infectious agents
  - Protective measures
- Identification of patients and their gametes, zygotes and embryos
- Culture media preparation and quality control testing
- Handling of embryos, zygotes, oocytes and spermatozoa
- Oocyte retrieval
- Sperm preparation
- Insemination of oocytes
- Scoring for fertilization
- Embryo culture adn transfer
- Cryopreservation of gametes, zygotes and embryos
- Assisted hatching
- Preimplantation genetic diagnosis
- Quality control and quality assurance

Guidelines for good practice in IVF laboratories

3. Laboratory safety

3.1 Laboratory design

More specifically:

- The construction of the laboratory should ensure aseptic and optimal handling of gametes, zygotes and embryos during all phases of the treatment.
- Although no documented cases of viral cross-contamination due to air quality have been reported, high-efficiency particulate air and volatile organic compounds filtration of the air supplied to the laboratory and clinical procedure rooms should be considered to maintain clean conditions. In addition, overpressure of the laboratory could contribute to exclude contamination from external areas.

8. Sperm preparation

8.3 Where donor sperm is used, the necessary identifying information (donor code/clinic code) must be recorded. The definition of a unique European code is foreseen for the end of 2007 with implementation in 2008. From then, the unique European code must be used.

Guidelines for good practice in IVF laboratories

The present European situation and the policy adopted by the European parliament comprise a comprehensive management system to be a standard requirement for ART clinics. In this context, the ESHRE guidelines for good practice in IVF laboratories, together with the European Tissue Directives, no longer represent an option, but a prerequisite, to operate and provide the best clinical outcome in a safe working system.

Commission européenne

The legal framework
Issues

- Substantial differences in national legislations promote cross border reproductive care
- Particularly for egg donation or surrogacy
- Sometimes in bad conditions
    - Adverse outcomes of the procedures
    - Exploitation of vulnerable women
        - Lack on information (language)
        - Risks for repeated donation
        - Non access to healthcare after come back
    - no fair access to these treatments

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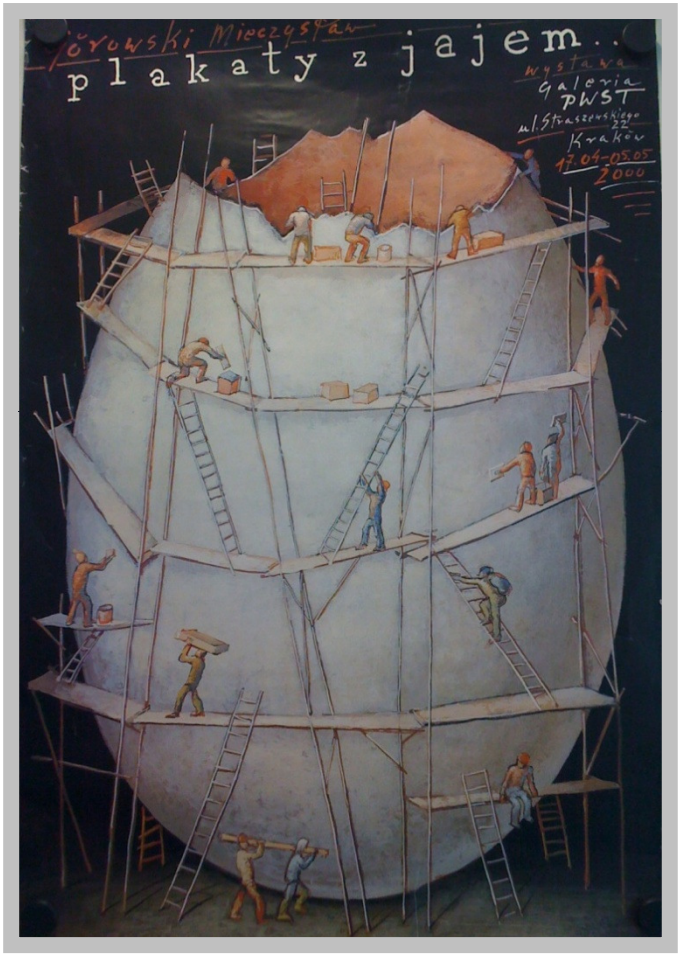
european society of human reproduction & embryology

Human body should not be a source of financial gains

Homogenisation of key principles
A dream?



Europe is currently in progress

- European directive for quality and safety in procurement processing and donation

  ➔ …
- European directive for free circulation of patients
- Currently each country are revising their legislation

Need for homogenisation, but many differences in

- Cultural values - ethical considerations
- Economic context
- State laicism
- public health issues

Work together defining the key principles