



european society of human reproduction & embryology

## European Assisted Conception Consortium (EACC)

### Full Consortium meeting ESHRE Barcelona

Tuesday 8 July 2008

ESHRE 2008 Annual Meeting in Barcelona

4 p.m. to 6 p.m. in Room P131+P132

CCIB - Forum



European Assisted Conception Consortium

## Agenda



European Assisted Conception Consortium

- |         |  |
|---------|--|
| 4.00pm  | Wellcome and opening address (J. Van der Elst)   |
| 4.15pm  | EACC board - evolution from start till today (A. Sunde)<br>EACC origin and objectives remembered<br>EACC board and membership today  |
| 4.30pm  | EACC achievements over the last year   |
| 4.45pm  | Follow up since last Full Consortium meeting of 12 February 2008, Brussels (TBA)<br>Follow up on issue of communication<br>Follow up on issue of different implementation in member states<br>Follow up on EC's competent authorities meeting, 29-30 May 2008<br>Follow up on coding |
| 5.30pm  | Looking ahead (J. Van der Elst)  |
| 5.55 pm | Closing remarks and adjourn (J. Van der Elst)  |



european society of human reproduction & embryology

## EACC: origins remembered

- European Assisted Conception Consortium
- Joint venture between ESHRE and HFEA
  - ESHRE = European Society for Human Reproduction and Embryology
  - HFEA = Human Fertilisation and Embryology Authority (UK)
- Not - for - profit initiative
- Established at ESHRE 2005 Copenhagen
- Member state organisation; 3 members per member state
  - Two IVF professionals (1 clinician, 1 embryologist)
  - One regulator



## EACC: objectives remembered

- Bring together IVF professionals and regulators from member states
- Communication between member states
  - To share experience and best practice
  - To search for continued improvement
  - Give advice to members setting up a competent authority
  - To develop position papers /newsletter/annual reports
- Communication to European Commission
  - seek channel for working together with the Commission to support implementation of the Directive
  - *present joint position of regulators and IVF professionals*
  - give expert advice to EC



## EACC board from start till today



- First board was installed at ESHRE Copenhagen 2005
  - Board members: Angela McNab, Bernard Loty, Ioannis Messinis, Anna Veiga, Josiane Van der Elst
- Board was installed for 2 years (terms of reference)
- 2007: voting on continuation and extension
  - Proposal for Board to continue accepted
  - New executive members (Arne Sunde, Cristina Magli, Basil Tarlatzis)
  - Chair continuing for a further year beyond the original term upon board's request
- 2008: voting on continuation, extension and chair (votes due by 27 June 2008)
  - Proposal for Board to continue accepted
  - New executive member: Edgar Mocanu (Ireland) – clinician
  - New Chair: Josiane Van der Elst



## EACC Board today

→ Six IVF professionals

→ Clinicians

- Ioannis Messinis (Greece)
- Edgar Mocanu (Ireland)



Josiane Van der Elst



Ioannis Messinis

Edgar's  
Happy picture

→ Embryologists

- Cristina Magli (Italy)
- Arne Sunde (Norway)
- Anna Veiga (Spain)
- Josiane Van der Elst (Chair) (Belgium)



Cristina Magli



Anna Veiga



Arne Sunde

→ Two regulators

- Bernard Loty (France)
- Basil Tarlatzis (Greece)



Bernard Loty



Basil Tarlatzis



## EACC past chair



European Assisted Conception Consortium

Thank you so much for having been  
an inspiring example  
of how to go on



Angela McNab (UK)



European society of human reproduction & embryology

## EACC membership today



European Assisted Conception Consortium



European society of human reproduction & embryology

## EACC membership today



European Assisted Conception Consortium

- 27 EU Member States
  - 21 represented in EACC (see list on ESHRE website – link EACC)
  - 6 not represented yet: Malta, Estonia, Latvia, Lituania, Romania, Bulgaria
- Plus Norway (EEA – falling under EUTCD)
- Non-EU Members that have joined for information
  - Montenegro
  - Serbia
  - Switzerland
- If your member state is not on the list yet, but you are here

please come forward



european society of human reproduction & embryology

## EACC membership today



European Assisted Conception Consortium

- No regulators yet identified for 8 of the 21 represented

member states

- Austria
- Cyprus
- Czech Republic
- Italy: now identified !!
- Luxemburg
- Portugal
- Slovakia
- Spain
- Sweden

Ask IVF Professionals

Ask EC ( who is on EC's Regulatory Committee for these member states)



european society of human reproduction & embryology

## Agenda



- 4.00pm Wellcome and opening address (J. Van der Elst)
- 4.15pm EACC board - evolution from start till today (A. Sunde)  
EACC origin and objectives remembered  
EACC board and membership today
- 4.30pm EACC achievements over the last year (C. Magli)
- 4.45pm Follow up since last Full Consortium meeting of 12 February 2008, Brussels (TBA)  
Follow up on issue of communication  
Follow up on issue of different implementation in member states  
Follow up on EC's competent authorities meeting, 29-30 May 2008  
Follow up on coding
- 5.30pm Looking ahead (J. Van der Elst)
- 5.55pm Closing remarks and adjourn (J. Van der Elst)

European Assisted Conception Consortium



European Society of Human Reproduction & Embryology

## EACC Achievements over the last year



- Full EACC Consortium meetings
  - Lyon, July 2007 (ESHRE)
  - Brussels, 12 February 2008
    - welcome and update on EACC (A. McNab - chair)
    - Update on EUTD implementation (J. Van der Elst)
    - Update from European Commission (T. Brégéon)
    - Update from EUSTITE project (Deirdre Fehilly)
    - Break out Groups (in parallel)
      - a) how to improve communication from EACC meetings to wider group of regulators and professionals
      - b) What questions would EACC like to suggest European Commission raise in questionnaire to competent Authorities or at next competent Authorities meeting.
  - Barcelona, July 2008 (ESHRE)

European Assisted Conception Consortium



European Society of Human Reproduction & Embryology

## EACC Achievements over the last year



European Assisted Conception Consortium

- EACC Executive Committee meetings (Board meetings)
  - 7 March 2007, Grimbergen
  - 4 June 2007, Paris, Agence de Biomédince
  - 3 October 2007, Brussels
  - Teleconference 24 June 2008
- EACC reporting to ESHRE's Executive Committee
  - Saturday 17 March 2007, ESHRE Central Office , Grimbergen
  - EACC representation by J. Van der Elst (Belgian local)
  - Explain actions of EACC
  - Seek continued ESHRE support
    - website, travel grants for EACC consortium members,
    - defend necessity to continue EACC as an ESHRE – linked body



European Society of Human Reproduction & Embryology

## EACC Achievements over the last year



European Assisted Conception Consortium

- EACC Executive Committee's delegation's meeting with European Commission, Directorate General Health and Consumer protection (SANCO)
  - 27 September 2007  
Feedback from ESHRE full consortium meeting
  - 3 October 2007  
To keep attention of EC focused on giving the necessary attention on reproductive tissues and cells in regulatory committees' meetings
    - EACC recognized as representative of ART professionals
    - Present position of ART professionals
    - Provide advice as experts in discussions on air quality, coding, adverse incident reporting



European Society of Human Reproduction & Embryology

## EACC Achievements over the last year



- Input into European Commission's work on coding European Fertilisation and Conception Consortium
  - Participation in CEN standardisation workshop on coding, Brussels
  - EACC representation by J. Van der Elst (Belgian local)
    - 13 April 2007
    - 21 May 2007
    - 5 September 2007
    - 20 November 2007
    - 22 February 2008
    - 25 April 2008



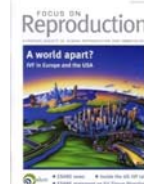
## EACC Achievements over the last year



### Publications

- EACC Newsletters 1, 2 (September 2007, January 2008)
- Focus on Reproduction
  - ESHRE /EACC position paper on the EU Tissues and Cells Directive EC/ 2004/23
  - Revised guidelines for good practice in IVF laboratories  
M. Cristina Magli, Etienne Van den Abbeel\*, Kersti Lundin,  
Dominique Royere, Josiane Van der Elst and Luca Gianaroli  
for Committee of the Special Interest Group on Embryology
  - Simon Brown's report on the EACC Full Consortium of 12 February in Brussels

European Fertilisation and Conception Consortium



## Agenda



4.00pm	Wellcome and opening address (J. Van der Elst)	European Assisted Conception Consortium
4.15pm	EACC board - evolution from start till today (A. Sunde) EACC origin and objectives remembered EACC board and membership today	
4.30pm	EACC achievements over the last year (C. Magli)	
4.45pm	Follow up since last Full Consortium meeting of 12 February 2008, Brussels (TBA) Follow up on issue of communication Follow up on issue of different implementation in member states Follow up on EC's competent authorities meeting, 29-30 May 2008 Follow up on coding	
5.30pm	Looking ahead (J. Van der Elst)	
5.55 pm	Closing remarks and adjourn (J. Van der Elst)	



## Follow up on Communication



- It was recognised that members from professional groups try to circulate information to their colleagues,
- more difficulty getting involvement when there is no contact or communication with a Competent Authority.
- It was agreed that one way EACC could assist would be to issue a **one page summary** of information after each meeting for members to then circulate all colleagues and Professional Bodies Societies.
- It was also agreed to ask EC to suggest Competent Authority make contact with their Professional Bodies as soon as possible.
- **Sent by mail 4 July**



## Follow up on implementation in Member States

1. Has implementation been done?
2. Air quality required?
3. Serology “at the time of donation”?
4. Is IUI under the directive?

## Ireland (source Tim Dineen, Edgar Mocanu)



- 1) **Yes**, all 3 directives have been transposed into Irish law.
- 2) Our competent authority has specified Grade D air quality.

Initially they were looking for GMP specifications, e.g. air locks, air pressures etc. But following a meeting with the fertility societies, they have relaxed the expectations to Grade D air in terms of microbial monitoring only. At the same time, 3 clinics have plans in place for up-grading the labs, which include plans for air locks etc.

- 3) Serology is carried out at first consultation and within 30 days of an egg collection.

Serology must be carried out for each egg collection.

The length of time that the serology test is valid for will be re-visited in 12 months time when the directive has been implemented in other member states.

- 4) Yes, IUI is within the remit of the directive. In terms of air quality, Grade D is required similar for IVF. For serology, testing is carried out at first consultation and this result is valid for 6 months.

There are now a number of clinics that carried out IUI treatment cycles only that have decided not to continue offering the service because of the need to up-grade labs. As a result, these couples are being transferred to clinics offering full ART services.

## UK (source Dave Morroll)

- 1) Has implementation of directives been done?

**YES** - THESE ARE WRITTEN AS STANDARDS AND INCORPORATED INTO THE CODE OF PRACTICE OF THE UK HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY; INSPECTION AGAINST THESE STANDARDS BEGAN LAST YEAR AND LICENCES ISSUED.

- 2) Air quality required?

"Wherever practical, the centre should carry out procedures involving the processing of gametes or embryos in an environment with air quality of **at least Grade C in the critical work area**. The centre should strive to maintain a background environment of Grade D air quality in laboratories in which gametes or embryos are processed".

"Where it is not practical to carry out a procedure involving the manipulation of gametes or embryos (for example, ICSI or blastomere biopsy) in a Grade C environment, the procedure should be carried out in an environment of at least Grade D air quality."

MONITORING AND VALIDATION IS REQUIRED



## UK (source Dave Morroll)

- 3) Serology "at the time of donation"? How defined?

"Where individuals are considering donation, Centres shall ensure: (1) that appropriate screening tests have been performed and are recorded, (2) that appropriate consideration has been given to the suitability of the Donor, including an assessment of any risks associated with using gametes or embryos from that Donor to the health or welfare of recipients or resulting children.

A LATER GUIDELINE POINTS TO GUIDANCE FROM PROFESSIONAL BODIES, THOUGH THESE DO NOT ADDRESS EXPLICITLY WHEN TESTS SHOULD BE DONE.

- 4) Is IUI under the directive?

YES - IUI CENTRES MUST NOW BE LICENSED AND COMPLY IN THE SAME WAY AS FULL ART SERVICE



## Denmark (source Soren Ziebe, Marie Grøndahl )

1. **Yes**, EUTD has been implemented incl. the mother directive and TD1 plus TD2

2. Air quality: no specific requirements but monitoring needed

3. Serology:

Tests negative from a certified testlab; lab results not older than 24 month.

It is stated that the test should be done "prior" to aspiration.

In case of oocyte donation it should be done no more than 30 day before.

4) Is IUI under the directive? YES



## Norway (source Arne Sunde)

- 1) **Yes**, in effect as on June 1st 2008
- 2) No specific air quality defined but monitoring required
- 3) For partner donation (regular IUI/IVF/ICSI) tests should not be more than 12months old.

For semen donation: test at time of donation, new test after 6 months of quarantine. (Other types of donation forbidden)

- 4) If semen is processed according to standard SOP's and the prepared semen is not stored, IUI is not regulated by the Directive.

Processing and short incubation prior to insemination is not defined as "storage".

## Finland (source Pirkko Kulomaa )

- 1. **Yes**, implementation has been done and the first inspections have been made for all applicant tissue establishments during this spring.
- 2. Air quality:
  - All cell work is carried out in the laminar flow , also IUI,
  - in the inspection the background air D seemed to be sufficient (at least for now).
  - It has to be monitored in certain intervals (not defined).
  - ICSI can be done outside laminars.
- 3. Serological testing varies generally between 12 to 18 months in Finnish clinics, but this will be defined later according to the future views of the meetings of EU representatives.
- 4. IUI under the directive, serology and air quality



## Germany (source Ulrich Hilland)

- 1: **Yes**, the directives have been implemented by two laws. There are corresponding decrees by the German Federal Ministry of Health.
- 2: The regulations regarding air quality are implemented as laid down in the technical directive. Exemptions from air quality Grade A are mentioned explicitly for IVF and ICSI in explanatory statements accompanying the specific decree.
- 3: Serology has typically to be done at the time of donation and cells/tissues are only to be used for further handling if the results of the tests are present.  
  
In cases like ART the serology can be performed within seven days prior to donation (called "donation specimen").  
  
Serology has to be repeated at every egg retrieval/semen collection
- 4: Partner donation of sperm cells for IUI is included in the decree but presently under debate. The possibility is provided for the responsible gynaecologist to refrain from testing if the risk of cross-contamination and staff exposure is minimized by validated procedures



## Poland (source Rafal Kurzawa)



- **Yes**, EUTD implemented already in 2005, however, reproductive cells and embryos excluded from the Act.
- New IVF bill prepared by the Ministry of Health
  - generally no ART restrictions
    - cloning prohibited
    - penalties for discarding embryos
  - no regulations on air quality
  - serology and donation
    - double testing 6 months before donation and on donation
    - partner donation (IVF): 6 months before donation
    - partner donation (IUI): no tests
  - The bill awaits approval by the Government. Passing seems to be extremely difficult due to the objections of the Catholic Church.

## Slovenia (source Danica Avsec Letonja)

- 1) Fertility law since 2000, in accordance with EU directives
- 2) Air Quality as part of GLP
- 3) Serology at time of donation and 6 months later before donation of gametes  
Serology for all heterologous ART  
Q: also 6 months interval
- 4) IUI : yes , under law

## Slovak Republik (source Ladislav Marsik)

- 1) Has implementation of directives been done? - **yes**
- 2) Air quality required? - yes
- 3) Serology "at the time of donation"? How defined?

BWR, HIV1,2, HbsAg, HBC, anti HCV negat., second time after 6 months

- 4) Is IUI under the directive?

yes for serological testing, not completely for air quality

## The Netherlands (source Peter Kastrop, Liisa Kok)

- 1) **yes**
- 2) (yes), still under examination of a working group of the professional society
- 3) national policy (screening at least once a year) still accounts for IVF/ICSI treatments with partner donation.
- 4) yes, but no serological testing, but IUI is performed in licensed tissue establishments.



## France (source Dominique ROYERE)

- **YES** / DECRET 19.06.2008 PUBLISHED ON 21.06.2008
- 2) Air quality required? NOT INDICATED IN THE DOCUMENT BUT REFERRED IN "Arrêté relatif aux Règles de Bonne Pratique cliniques et biologiques d'assistance médicale à la procréation" 11.04.2008
- 3) Serology "at the time of donation"?  
Not defined in Implementation but rather in Good Laboratory practice Guideline
- 4) Is IUI under the directive? Yes at least concerning serological testing.

## Greece (source Basil Tarlatzis, Ioannis Messinis )

- 1. **Yes**, The EUTD has been implemented by Presidential Decree No 26/24 March 2008
- 2. Air quality is required as appears in the EUTD
- 3. Serology at time if donation? How defined?  
*Exams for HIV I, II, Hepatitis B, C the day of donation and 2-3 months before for female donors and 6 months before for male donors.*
- 4. IUI is under the directive.
- However the details concerning air quality, serology and IUI will be specified in the Presidential Decree that is currently being prepared by our National Authority on ART.

## Italy (source C. Magli, M. Costa, G. Scaravelli)

- 1) till now **only the mother Directive has been transposed** in Italy with a legislative Decree of the 6th November 2007 published, on the National G.U.n.261 9/11/2007. The two technique Directives n.2006/17/CE and 2006/86 CE are together in a single document and they are on their bureaucratic course and will be probably transposed and published within the end of 2008.( we hope next September!!)
- 2)The AIR quality required in the draft version of the technique directive n 2006/86/CE is grade A with a background at least grade D but there are exceptions that concern all the ART applications including IUI, in these conditions you are not obliged to have Air quality grade A or D these are:
  - - when you apply a validated process of microbial inactivation or final sterilization
  - - when you can demonstrate that contact with GRADE A air quality has bad effects on the tissues or cells you are treating
  - -when you can demonstrate that the application of those cells or tissues to the recipient has a very lower risk of bacterial or micotic infection transmission respect to the transplant of those cells or tissues themselves
  - - when it is not technically feasible to perform that procedure in a GRADE A Environment ( example when you can't utilize a specific equipment because it is not compatible with air A quality)



European Society of Human Reproduction & Embryology

## Italy (source C. Magli, M. Costa, G. Scaravelli)

- 3)Serology at the time of donation is mandatory but results of the tests are valid for six months.

The tests mentioned in the directive are : anti HIV,HBsAg, AntiHBc,Anti HCV It is specified that if the donor came from an endemic area of HTLV1 also this test should be performed

- 4) THE IUI is under the directive.

Serological testing are not mandatory if you use fresh semen

if you do cryopreservation of semen you are obliged to test the donor, but they are valid for six months.

In terms of air quality are valid the preceding exceptions.



European Society of Human Reproduction & Embryology

## Portugal (source Carlos Plancha, Carlos Calhaz-Jorge)

- 1) Implementation of directives is **on the way**:
  - - The Authority has been identified and has produced regulation according to the directives.
  - - Inspections and Licensing of the clinics expected to start in the future.
- 2) Air quality is required for the embryology lab:
  - - Air filtration required.
  - - Positive pressure desirable.
- 3) Serology is required for ART:
  - - Results valid during 6 months, so "at the time of donation" can be "in fact" until 6 months before.
  - - For third party donors is of course more strict.
- 4) IUI is considered under the directive:
  - - Regarding serological testing is the same as described in 3).
  - - Regarding air quality is less strict than for other ART (in the andrology lab air filtration is desirable, but not required).

## Sweden (source Julius Hreinsson)

- 1) Implementation of the directives is **not finalized**, however a proposal for a new law which will formally implement the directives is being processed by the Swedish parliament. (Date of implementation is constantly being delayed by a few months).
- 2) Air quality required? Not certain at this time, decision has not been taken.
- 3) Serology "at the time of donation"? Not currently defined in cases of own gametes.
  - 6 month rule for gamete donation, frozen sperm retest of donor.
  - Oocyte donation: two tests with 6 month intervals before donation.
- 4) IUI is under the directive both in terms of serological testing and in terms of air quality
  - Already now Swedish authorities have announced that IUI preparations at doctors offices in a small scale will probably have to stop unless the clinics invest a major effort in adhering to the demands of the directive.

## Implementation in Belgium



1. EU Directives: transposition is **on the way**, proposal in Senate
2. Air quality: A in D is the rule  
exceptions possible, but less than D background will be difficultly accepted
3. Serology: still debate on frequency
4. IUI: for air quality: not less than D  
  
for serology: if shown appropriate safety measures are taken maybe testing not necessary for partners

## No implementation yet

Spain (source Anna Veiga)

- The directive was transposed a long time ago but the competent authority has not yet been established for Assisted Reproduction

Hungary (source János Urbancsek, Peter Fancsovits)

- the implementation of the directive has not been done yet
- hungarian embryologists were informed about the directives and about the ESHRE position statement on an informal meeting.

Czech republic (source Tonko Mardesic)

- The directive has not been implemented yet in Czech republic .
- However, the law proposal for implementation is in final phase for the Czech parliament.

Cyprus (source Michael Pelekanos, Gabriel Kalakoutis)

- implementation of directives hasn't been done yet / maybe in December 2008.

## Agenda



4.00pm	Wellcome and opening address (J. Van der Elst)	European Assisted Conception Consortium
4.15pm	EACC board - evolution from start till today (A. Sunde) EACC origin and objectives remembered EACC board and membership today	
4.30pm	EACC achievements over the last year (C. Magli)	
4.45pm	Follow up since last Full Consortium meeting of 12 February 2008, Brussels (TBA) Follow up on issue of communication Follow up on issue of different implementation in member states Follow up on EC's competent authorities meeting, 29-30 May 2008 Follow up on coding	
5.30pm	Looking ahead (J. Van der Elst)	
5.55 pm	Closing remarks and adjourn (J. Van der Elst)	



## Follow up on May 2008 Competent Authorities' meeting

- Important differences in implementation in Europe probably due to different interpretation of the EUTD + unresolved questions have been identified at the EACC consortium meeting of 12 February 2008
- They were brought to the Commission's attention: A number of questions were identified to pass to European Commission for inclusion in the Competent Authority pre-meeting questionnaire or at the meeting itself.

They were as follows:



## List of questions handed over to EC

- How do you interpret the EUTD in relation to scope of application in ART ?
- Do you believe it includes regulation of embryos? How are you interpreting the term 'Direct use' in ART?
- What do you believe should be the key list of 'events' and 'reactions' covered under adverse events and adverse reactions?
- How do you interpret the definition of process under article 6?
- What arrangements are in place for "clinic closure" situation. Given the burden this may have on clinics have Competent Authority taken the arrangements for this to their level?

## List of questions handed over to EC

- What testing/screening Requirements are in place in your member state?  
How is reproductive tissue defined and managed (eg. Ovarian tissue) compared with reproductive cells? How are stored sperm from cancer patients (where there is no defined partner) managed?
- How do you define partner donation specifically in relation to same sex couples?
- How do you define banking?
- Do you include IUI in the scope of the Directive (eg. in terms of air quality, testing)
- How to ensure 'comparable quality' when member state have different implementation eg, on air quality or scope?

## List of questions handed over to EC

- What arrangements for third party agreements are in place in your member state? Are you finding providers such as courier companies or manufacturers unwilling to formally accept their responsibility for meeting all safety and quality requirements as expected under EUTD? Please give examples of any difficulties, or actions taken to resolve?
- Would you accept gametes/embryos from all member state regardless of a) how any one state has interpreted Directive or b) how far implementation has been progressed? If not do you believe patients, can be denied right to take their tissue or cells out of one member state to another for their own use?



european society of human reproduction & embryology

## List of questions handed over to EC

- In PGD do you agree that the extracted cells (not for human application) fall outside of the Directive?
- How are you identifying the Responsible Person – do you believe a non-medic can ensure procurement standards we met?
- How do you believe Competent Authority should keep centres/ establishments informed about progress with EUTD implementation, new standards, etc?



european society of human reproduction & embryology

## Feedback on CA meeting by Angela McNab

- A number of “hotspots” or areas of inconsistent interpretation have been presented by Angela :
  - Testing /screening arrangements,
  - third party agreements,
  - inclusion of embryos in the scope of the Directive,
  - the definition of “process”,
  - the inclusion of IUI in the scope,
  - and arrangements for clinic closure.
- Many member states are anxious that if one state interprets the Directive less widely/strictly than another then it will make transportation from one state to another of embryos very difficult.
- There was discussion on the issues and it was agreed that a subgroup might get together to manage these issues.
- Regulatory authorities were also encouraged to engage with the EACC and to support communication.



European society of human reproduction & embryology

## Agenda



European Assisted Conception Consortium

- |         |  |
|---------|--|
| 4.00pm  | Wellcome and opening address (J. Van der Elst)   |
| 4.15pm  | EACC board - evolution from start till today (A. Sunde)<br>EACC origin and objectives remembered<br>EACC board and membership today  |
| 4.30pm  | EACC achievements over the last year (C. Magli)  |
| 4.45pm  | Follow up since last Full Consortium meeting of 12 February 2008, Brussels (TBA)<br>Follow up on issue of communication<br>Follow up on issue of different implementation in member states<br>Follow up on EC's competent authorities meeting, 29-30 May 2008<br>Follow up on coding |
| 5.30pm  | Looking ahead (J. Van der Elst)  |
| 5.55 pm | Closing remarks and adjourn (J. Van der Elst)  |



European society of human reproduction & embryology

## Follow up on Coding

- EC has the duty to develop a unique European code for cells and tissues
- EC ordered a CEN workshop to propose a code
- CEN = European Committee for Standardisation (Comité Européen de Normalisation)
- Expert group of CEN was composed
  - studying coding requirements
  - looked at examples of existing codes: 3 systems were submitted
    - Italian coding system
    - Spanish coding system
    - ISBT 128
- A proposal has been delivered by the coding workshop to the EC
- This will now be further taken up by EC



## Coding: EXAMPLE – not to be distributed

EU DG SANCO WG

Country ID + TE

Unique Donation number

Product Code

**Variation 1:**

Globally unique donation, product & "key" codes

Country ID + CA + TE "key code"

Globally unique Donation Code

Globally unique Product Code

**Variation 2:**

National, regional, or local donation code + globally unique product & "key" codes

Country ID + CA + TE "key code"

National, Regional, or Local Donation Code

Globally unique Product Code

**Variation 3:**

National, regional, or local donation & product codes + "key" code

Country ID + CA + TE "key code"

National, Regional, or Local Donation Code

National, Regional, or Local Product Code



## Agenda



- 4.00pm Wellcome and opening address (J. Van der Elst)
- 4.15pm EACC board - evolution from start till today (A. Sunde)  
EACC origin and objectives remembered  
EACC board and membership today
- 4.30pm EACC achievements over the last year (C. Magli)
- 4.45pm Follow up since last Full Consortium meeting of 12 February 2008, Brussels (TBA)  
Follow up on issue of communication  
Follow up on issue of different implementation in member states  
Follow up on EC's competent authorities meeting, 29-30 May 2008  
Follow up on coding
- 5.30pm Looking ahead (J. Van der Elst)
- 5.55pm Closing remarks and adjourn (J. Van der Elst)

European Assisted Conception Consortium



European society of human reproduction & embryology

## Looking ahead



- Seeking your opinion on proposal for ESHRE Campus Workshops on the EU directives (N,E,S, W Europe) as a replacement of the February Full Consortium meeting
  - Centres opening doors?
- How to further increase and improve communication channels
  - One pager summary to continue
  - Mailing to EACC Consortium members at regular intervals?
  - Use discussion forum on ESHRE website? – moderation? – idea box?
- Regular briefing session of EACC Chair with ESHRE's Executive Committee
- Continue and strengthen link with European Commission DG SANCO
  - in particular ask facilitation by EC on how to start, continue or improve interaction with regulators in reproductive sector
- Any other suggestions?

European Assisted Conception Consortium



European society of human reproduction & embryology

## Closing remarks and adjourn



European Assisted Conception Consortium

- After ESHRE the new EACC board will come together
- Proposals done here to be worked out
- Briefing after Board meeting

**Hope to CU back all soon**



European Society of Human Reproduction & Embryology



European Society of Human Reproduction & Embryology

## UK (source Dave Morroll)

- 1) Has implementation of directives been done?

YES - THESE ARE WRITTEN AS STANDARDS AND INCORPORATED INTO THE CODE OF PRACTICE OF THE UK HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY; INSPECTION AGAINST THESE STANDARDS BEGAN LAST YEAR AND LICENCES ISSUED.

- 2) Air quality required?

THE STANDARD 9.4.3 STATES THAT "Wherever practical, the centre should carry out procedures involving the processing of gametes or embryos in an environment with air quality of **at least Grade C in the critical work area**. The centre should strive to maintain a background environment of Grade D air quality in laboratories in which gametes or embryos are processed".

IN ADDITION, STANDARD 9.4.4: "Where it is not practical to carry out a procedure involving the manipulation of gametes or embryos (for example, ICSI or blastomere biopsy) in a Grade C environment, the procedure should be carried out in an environment of at least Grade D air quality."

MONITORING AND VALIDATION IS REQUIRED



## UK (source Dave Morroll)

- 3) Serology "at the time of donation"? How defined?

STANDARD 7.6.7 STATES "Where individuals are considering donation, Centres shall ensure: (1) that appropriate screening tests have been performed and are recorded, (2) that appropriate consideration has been given to the suitability of the Donor, including an assessment of any risks associated with using gametes or embryos from that Donor to the health or welfare of recipients or resulting children.

A LATER GUIDELINE POINTS TO GUIDANCE FROM PROFESSIONAL BODIES, THOUGH THESE DO NOT ADDRESS EXPLICITLY WHEN TESTS SHOULD BE DONE.

- 4) Is IUI under the directive? (if possible : in terms of serological testing? in terms of air quality?)

YES - IUI CENTRES MUST NOW BE LICENSED AND COMPLY IN THE SAME WAY AS FULL ART SERVICE

