

Authority Meeting

Wednesday 7 July 2010
Glaziers Hall, London

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to prevent interference with the audio recording



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Item 1

Welcome, Apologies and Declarations of Interest

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Housekeeping

- **Fire alarm:** No tests are planned today. If you hear the signal, follow the green 'exit' signs
- **Toilets:** Downstairs in main foyer area

Item 2

Minutes of 12 May 2010



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Item 3

Chair's Report

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Item 4

Chief Executive's Report

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Business Plan 2010/11

- New restrictions on:
 - Recruitment
 - Pay freeze
 - Expenses
 - Consultancy
 - Communications
- 3% sector-wide budget cut (GIA only, £64k)
- £0.9m approved by DH for project business cases (confirmed)

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Operational Efficiency Programme Returns

January

- Three year funding - 2009 report by central government

March

- SSRB review of senior remuneration in the public sector

April

- Very Senior Manager's Pay Framework-Job Evaluation

May

- CO Request - High Earner Disclosure
- ALB review: HFEA functions for comment
- Revised Budget 2010-11 and Implementing Efficiencies

June

- ALB Review - HFEA Functional Analysis, a request for information
- Implementing Efficiencies - Reporting on Consultancy Spend
- Comprehensive headcount and other management information
- Implementing efficiencies to support £6bn savings
- Equality and Diversity information
- Pension scheme

July

- 2010 Central Government Benchmarking Exercise

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In/Out

- **Out:**

- Fees review (in 2010/11, unit costs of regulatory activities only)
- Evaluation of 8th Code
- PREP 2
- Thematic reviews
- Joint work with other (UK) regulators
- Inspectors' notebook improvements
- Investors in People
- Work on back-office functions
- Review of HR and Finance software
- Pre-1991 register (Donor Link)
- EU coding and traceability
- Treatment abroad
- Equal access to treatment (other Equality Act work stays)
- PGS element of PGD decision-making project.

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In/Out (continued)

- **In:**
 - QMS
 - Revised phase 1 of fees review (unit costs)
 - Database redevelopment project
 - Risk Tool Phase 2
 - Online Applications Phase 2
 - ELP evaluation
 - P2010 evaluation
 - Records management
 - Attitude survey/polling (reduced but almost completed anyway)
 - Donation review (reduced)
 - Equality Act 2010

Finalising the Business Plan

- White paper/ALB Review
- Final revisions to financial section
- Revised draft to Authority & DH for approval within next 2 weeks
- Publication (pdf on website as usual)

Delivery

- Q1 ended on 30 June, so 9m for delivery
- Project recruitment started
- Weekly oversight by SMT of big projects and resourcing
- Ongoing project management via Programme Board, reporting to CMG
- Continued CMG approval for all business cases and resources.

Item 4

Directors' Reports

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Item 5

Recommendations from the Hampton review working group

Juliet Tizzard

Acting Director of Strategy & Information

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Timeline

May 2009

→ Hampton Review team visits HFEA

December

→ Hampton Review report published

Jan 2010

→ Authority discusses recommendations

May

→ Members group meets

July

→ Authority agrees further work

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Members' working group

Ruth Fasht, chair

Debbie Barber

Andy Greenfield

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Areas of work

Advice and guidance

Transparency and our relationship with the sector

Data collection and information usage

Compliance and sanctions

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Recommendations

Advice and guidance

1. Develop methods for more effective working between Policy and Compliance in the development of guidance for the sector.

Head of Policy
Head of
Inspection

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Recommendations

Transparency and our relationship with the sector

2. Consider ways of addressing the perception of bias through communications activities.

Head of Communications

3. Ensure that impact assessments are fully embedded in the policy-making process.

Head of Policy

5. Consider whether inspectors need training and supervision to maintain a balance between support and compliance roles.

Director of Compliance

Recommendations

Data collection and use of information

7. Develop an analytical function to make better use of the data that we hold.

Head of Bus.
Intelligence

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Recommendations

Compliance and sanctions

9. Evaluate how risk-based our compliance cycle is as part of the P2010 evaluation.

Director of
Finance and
Facilities

10. Evaluate how useful our application forms are for research applicants as part of P2010 evaluation

Director of
Finance and
Facilities

11. Consider combined inspections for centres with treatment and research licences.

Director of
Compliance

Recommendations

Compliance and sanctions cont.

13. Consider whether the number of unannounced inspections could be doubled.

Director of Compliance

14. Consider actions to address the perception that sanctions take too long to be applied.

Director of Compliance

15. Evaluate the consistency and fairness of licensing decisions, and the use of sanctions, as part of the evaluation of the new licensing arrangements.

Director of Compliance

Recommendations

Compliance and sanctions cont.

16. Ensure that the process for applying sanctions is made clear to the sector in the C&E policy and consistency of use is evaluated

Director of Compliance

17. After the licensing evaluation, consider whether we should be less concerned about availability of services when considering licence suspension

Director of Compliance

18. Consider whether issues which are the subject of an alert should become inspection themes.

Director of Compliance

Item 6

Multiple Births Update

Helen Richens
Policy Manager

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Multiple pregnancy is the **single biggest risk** of fertility treatment to mother and child



The policy

Outcome based

- Yearly maximum multiple birth rate
- Aim to reduce IVF multiple birth rate to **10%**

Clinics' discretion

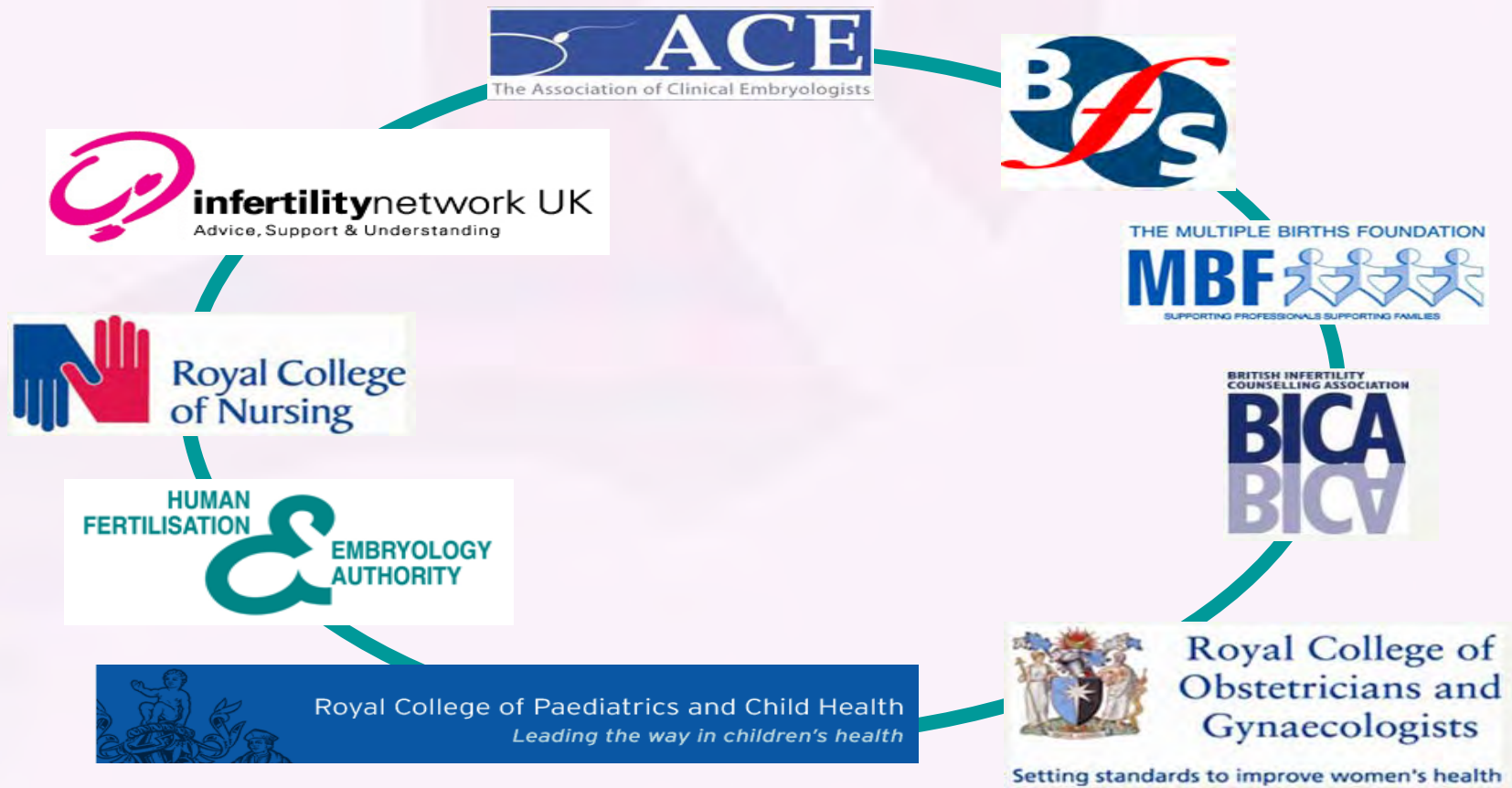
- All centres must have their own '**multiple births minimisation strategy**'

National strategy

- Policy forms part of a wider national strategy involving **professional bodies, patient groups and funding bodies**

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Multiple births stakeholder group



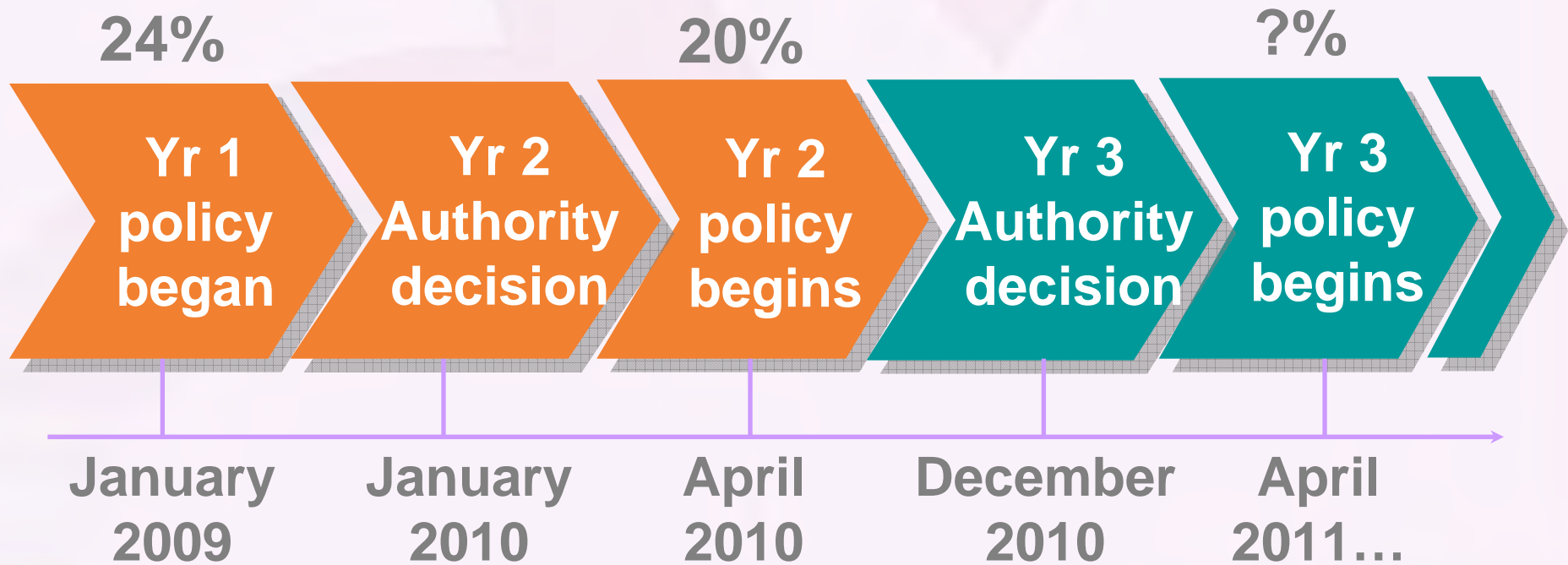
Professional education

Patient education

Data analysis and presentation

Funding for treatment

Where are we now?



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Year 1 snapshot

All centres have a
minimisation strategy?



Centres predicted to meet
the Year 1 target of 24%?

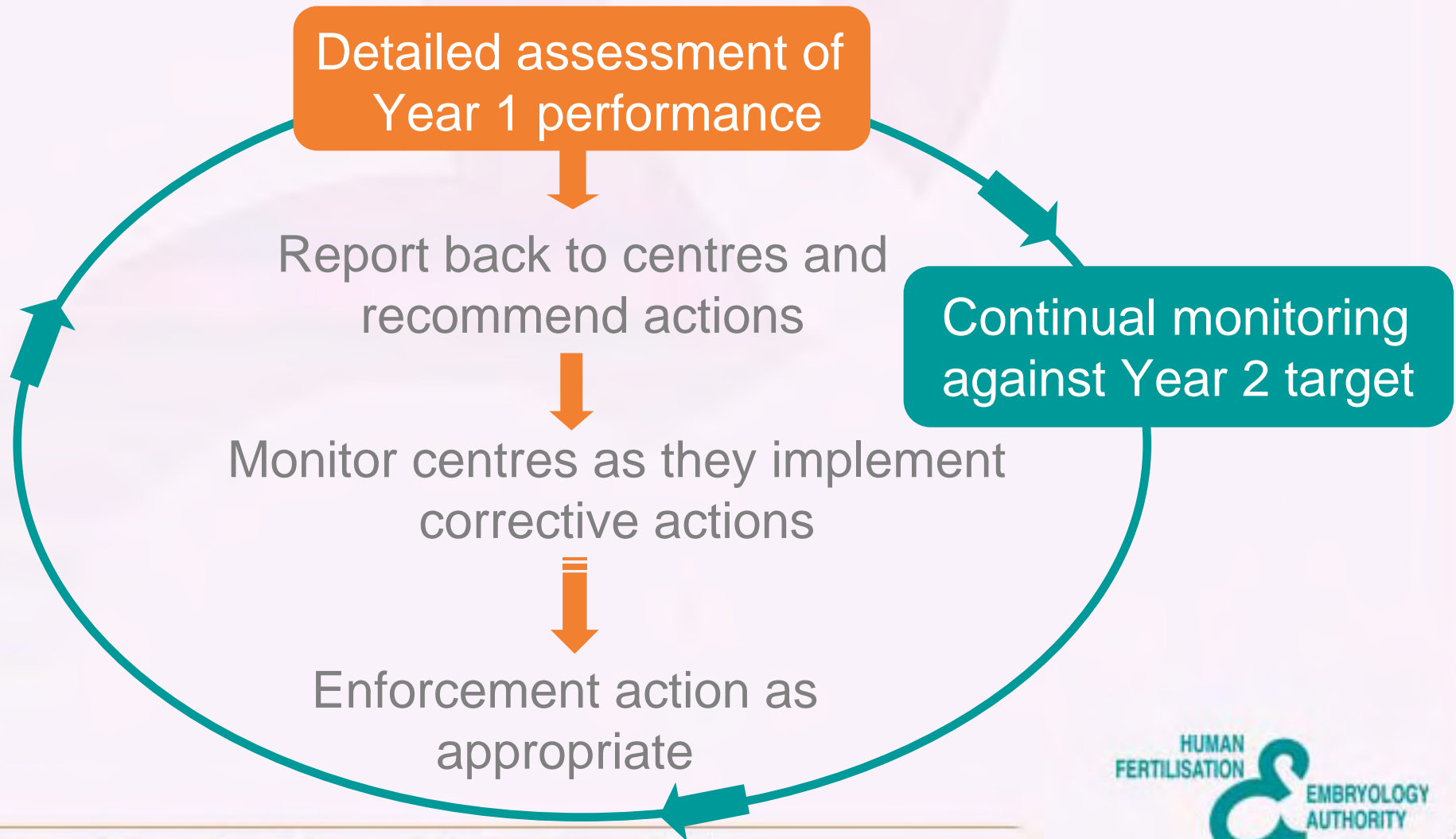
Over 2/3 of centres
Many significantly below 24%

Overall predicted multiple
birth rate for 2009?

~24% multiple births
Difference between women
aged <35 and women >35

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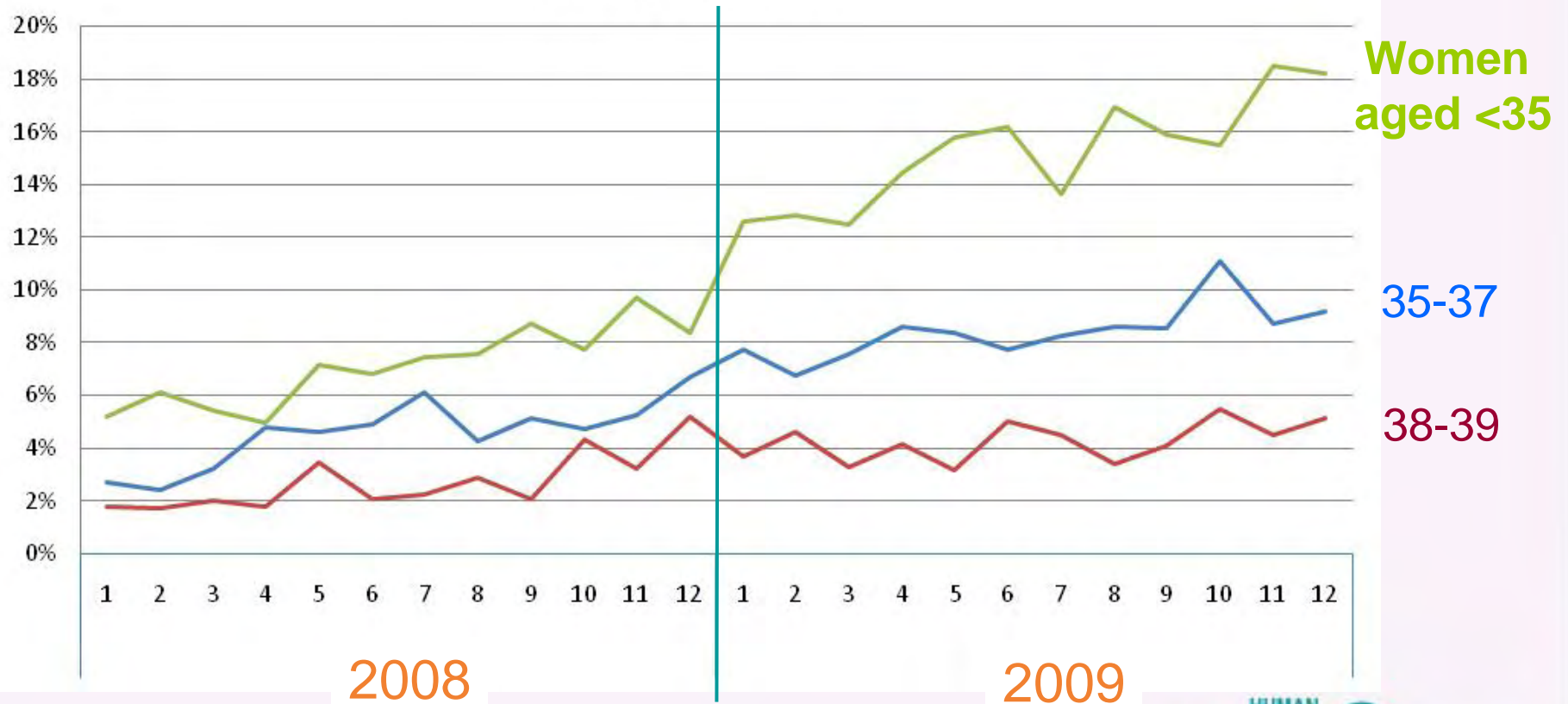
Monitoring and enforcing policy



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eSET is increasing

Proportion of embryo transfers that are elective single embryo transfer



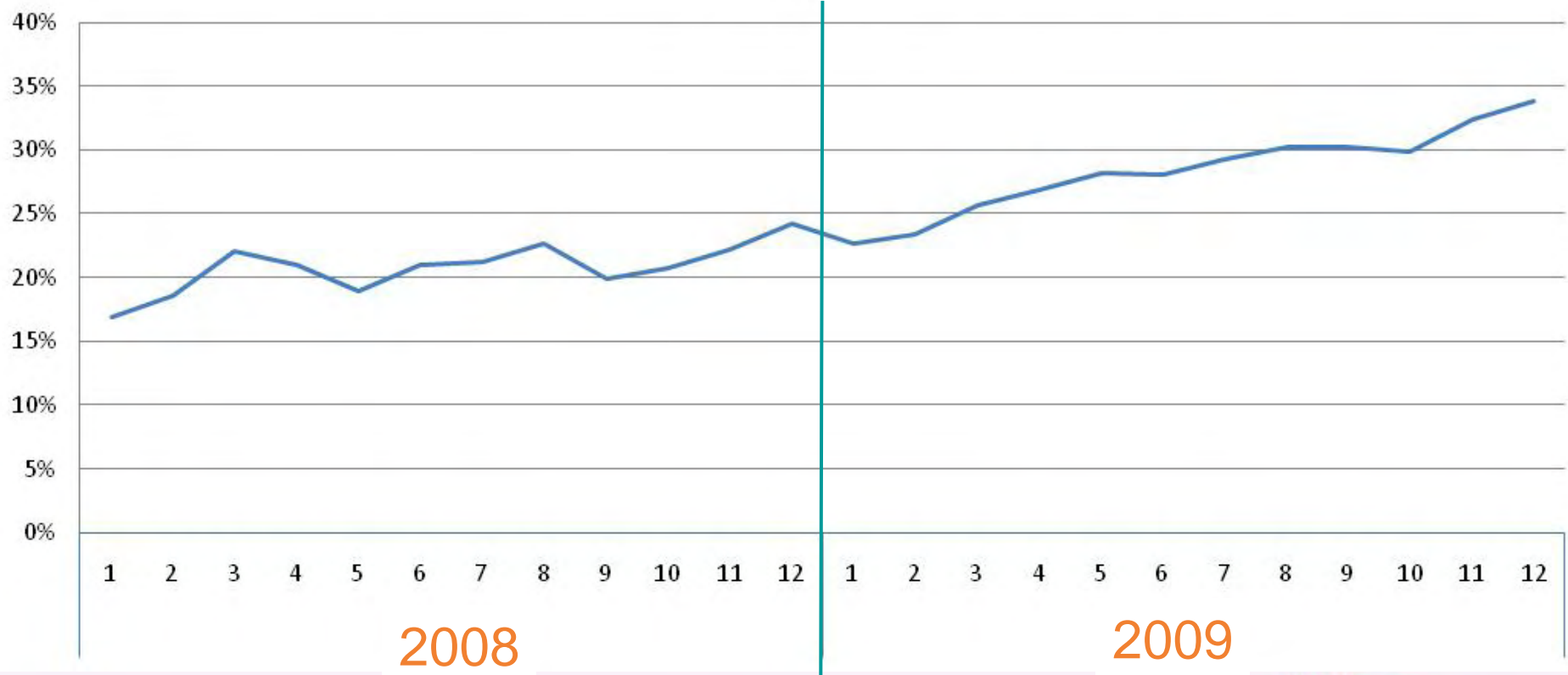
Data from fresh treatment cycles extracted from HFEA Register 18/03/2010. 2009 data is unverified



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Blastocyst transfers are increasing

Proportion of embryo transfers that are blastocyst transfers
(all ages)

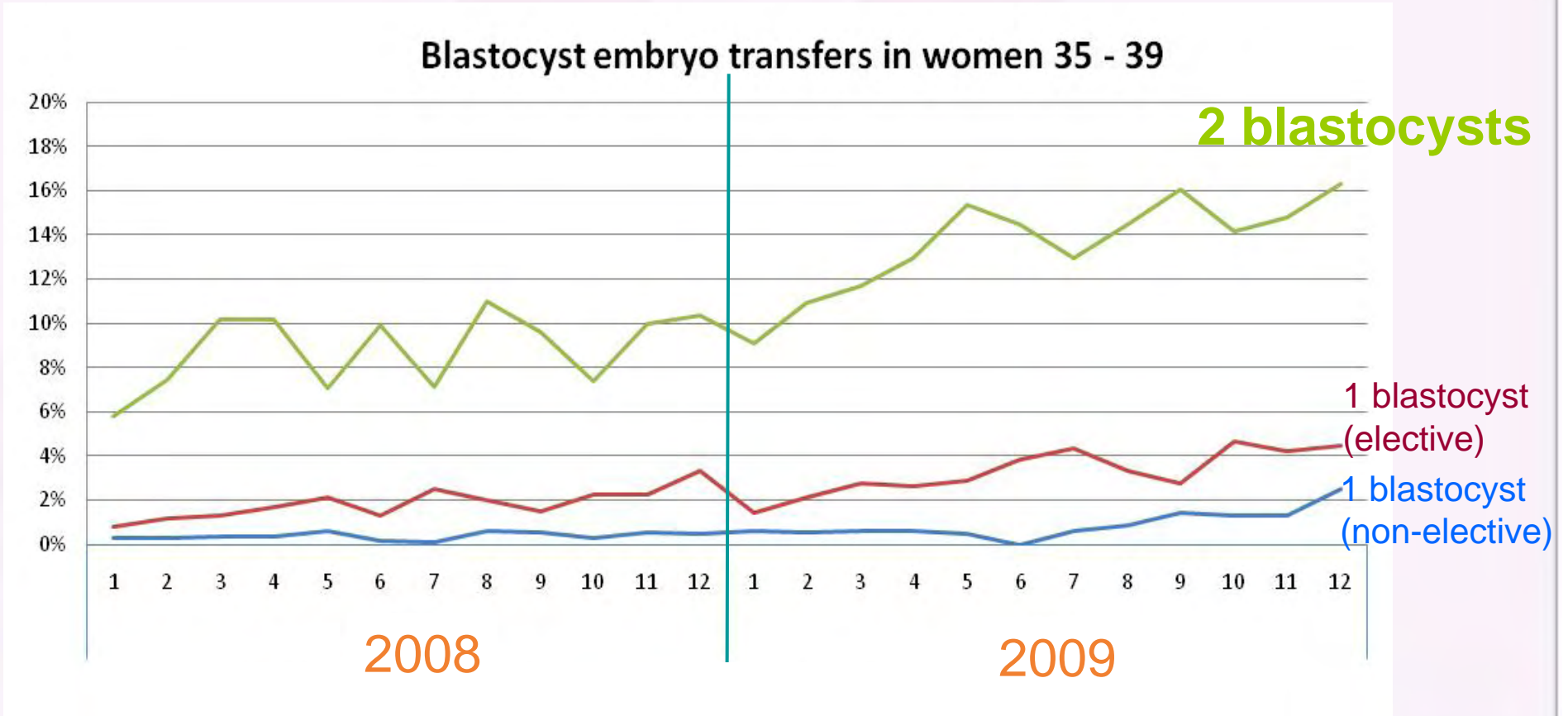


Data from fresh treatment cycles extracted from HFEA Register 18/03/2010. 2009 data is unverified



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Double blastocyst transfers are increasing in women aged over 35



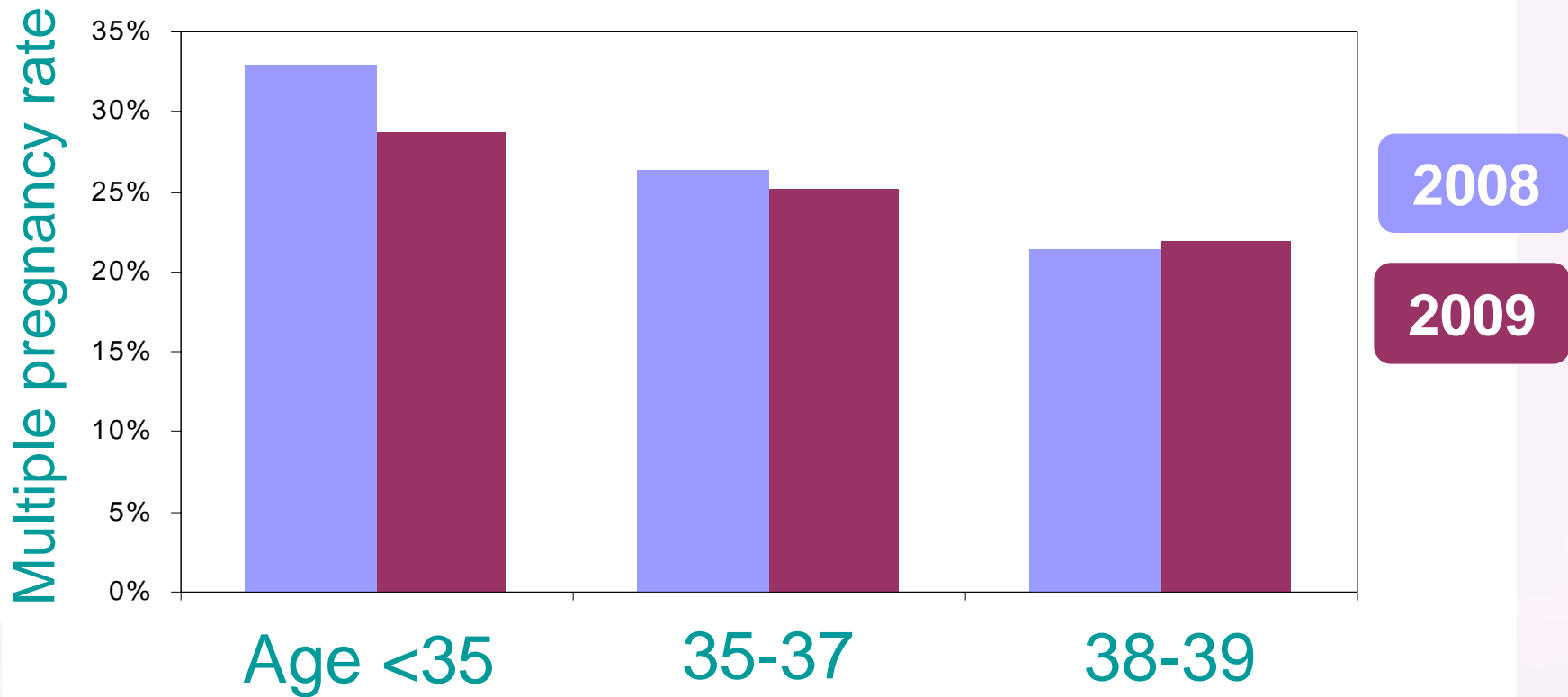
Data from fresh treatment cycles extracted from HFEA Register 18/03/2010. 2009 data is unverified



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Multiple pregnancy rate

Multiple pregnancies in 2009 compared to 2008

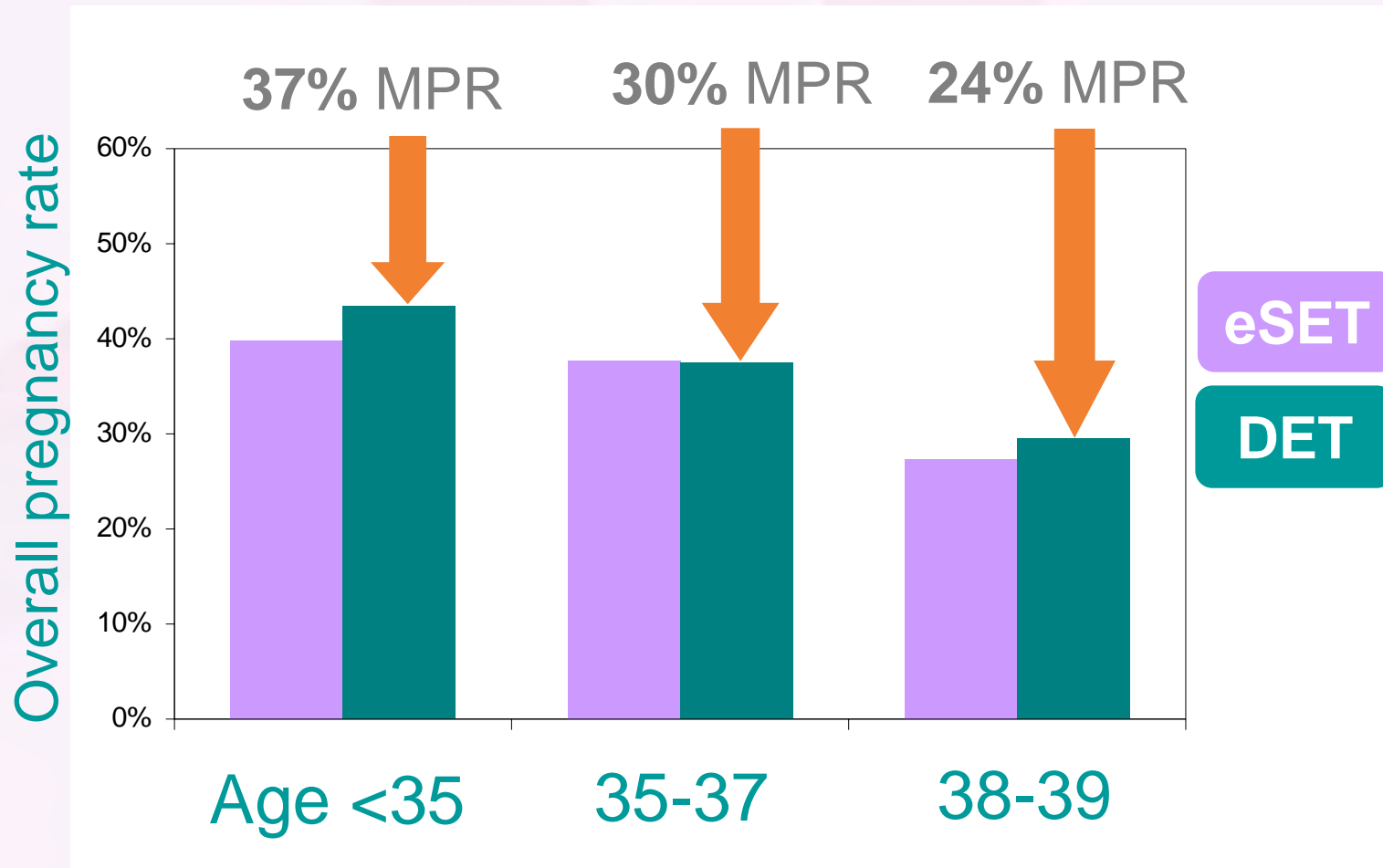


Data from fresh treatment cycles extracted from HFEA Register 18/03/2010. 2009 data is unverified



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2009 pregnancy rates for eSET vs DET

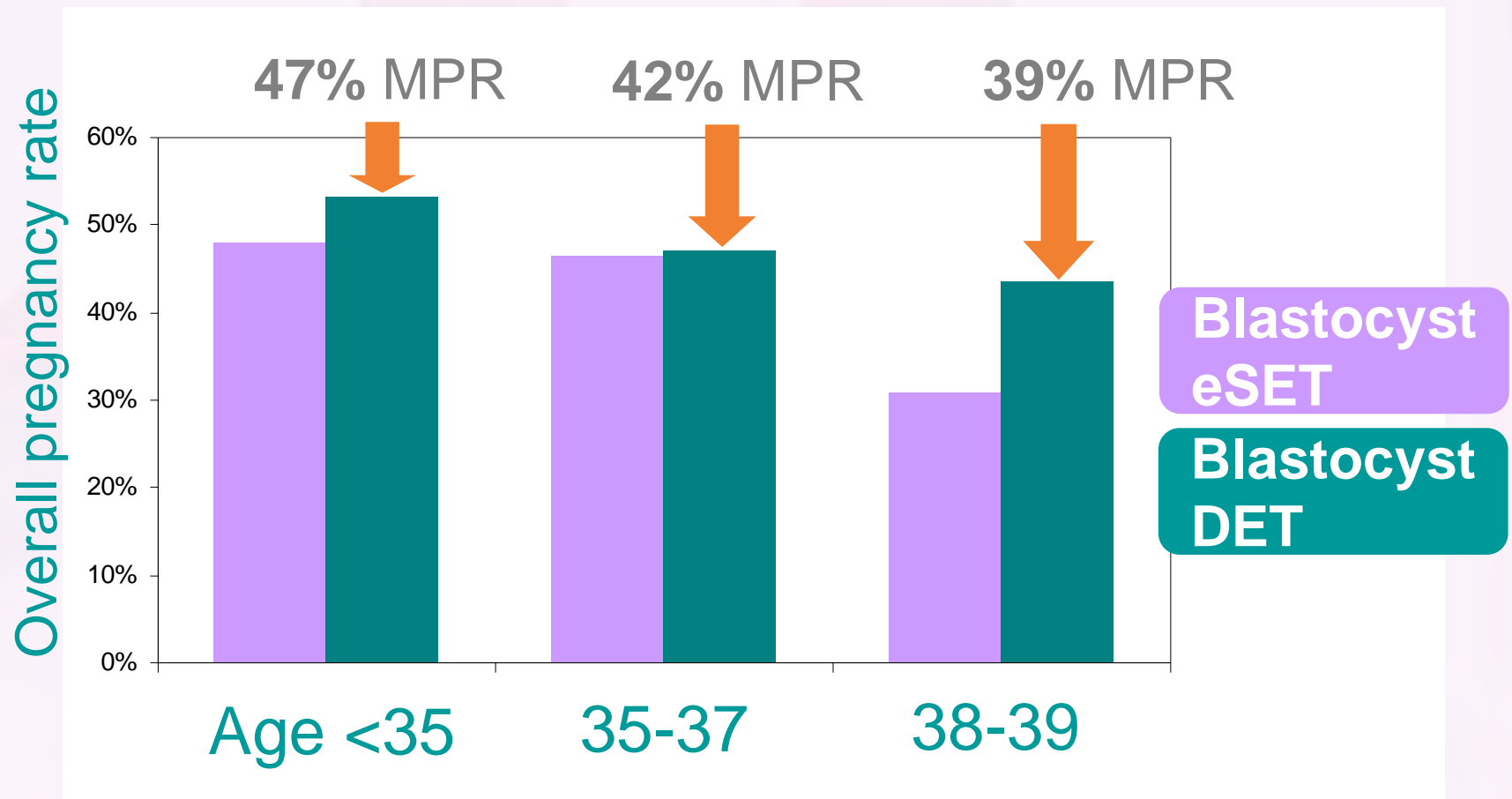


Data from fresh treatment cycles extracted from HFEA Register 18/03/2010. 2009 data is unverified



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2009 pregnancy rates for blastocyst eSET vs DET



Data from fresh treatment cycles extracted from HFEA Register 18/03/2010. 2009 data is unverified



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What do centres think?

Develop strategy

- BFS/ACE guidelines
- Analyse own data
- Embryo grading & freezing

Implement strategy

- Strong, consistent message to patients

Audit strategy

- Nearly all audited and 1/2 modified strategy

Issues

- Lack confidence
- Set cautious criteria
- Training/guidance

- Poor patient uptake
- NHS funding/cost
- Staff training

- Expand patient criteria
- Alter embryo criteria
- Patient information

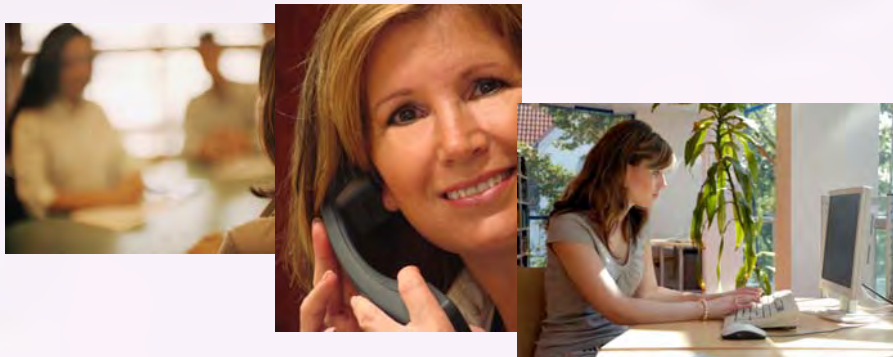
Understand, support & enforce policy!

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What do patients think?

Patients who choose eSET

- Strength of message
- Trust clinic's recommendation
- Concerned about risks



Patients who choose DET

- Increase success rates
- Avoid further treatment
- Risks acceptable to them

Change their mind?

- Better SET success rates
- Less expensive treatment
- More funded cycles

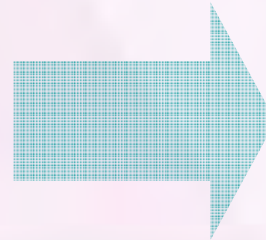
Patients want more information!

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Focus and challenges of the policy

Year 1

- Changing attitudes
- Processes in place
- Supporting centres



Year 2

- Expect to see progress
- Share lessons & data
- Monitor, support centres
- Enforcement

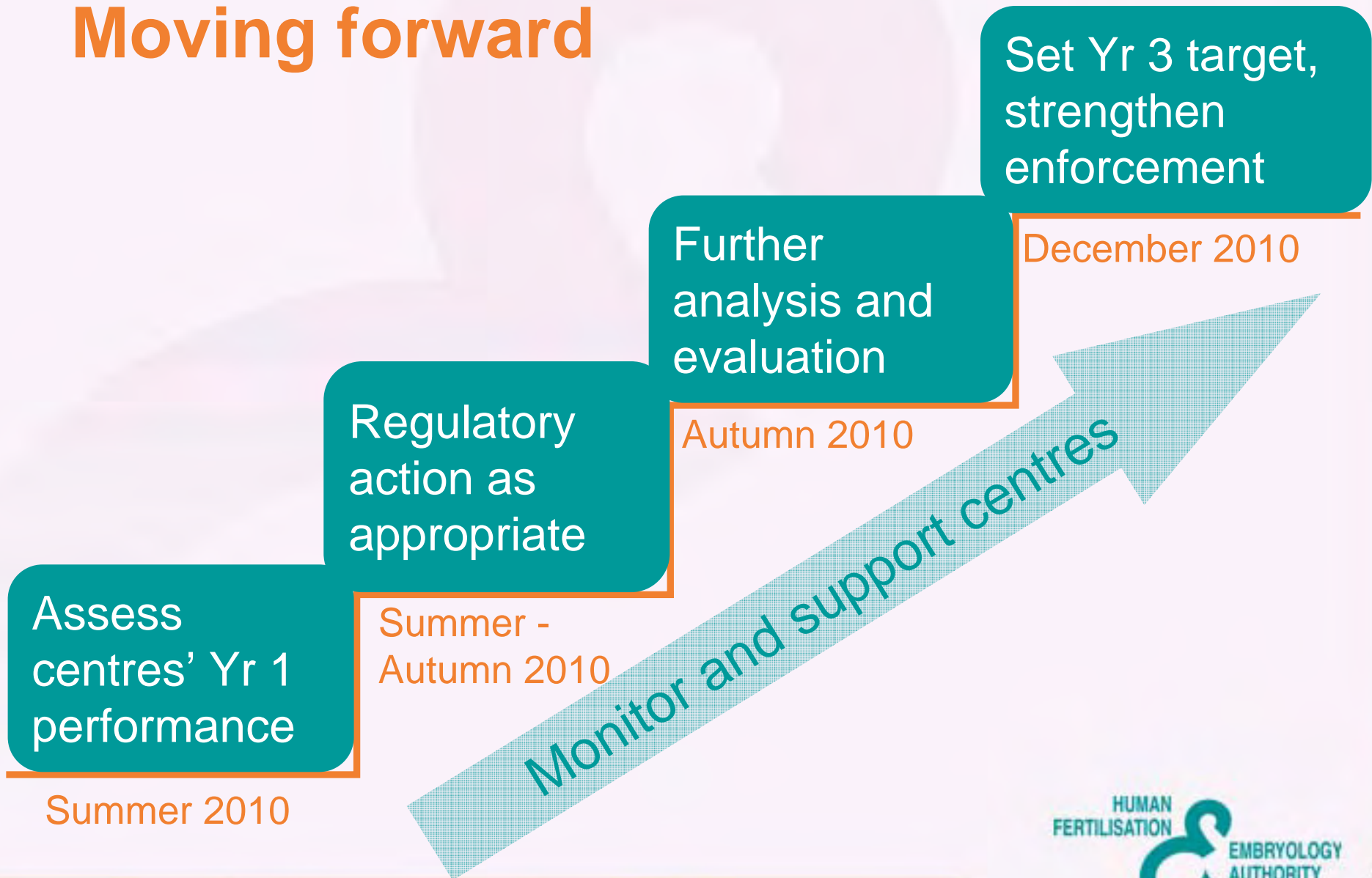
Supporting centres

Proportionate & fair regulation



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Moving forward



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Discussion

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Item 7

Translation and Interpretation policy

Sharon Neaves
Communications Manager

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Our legal obligations



- Protection of rights of non-English speakers
- Equality Act 2010
- Welsh language Act

Clinics' responsibility



- Our own material & duties of clinics
- Code of Practice

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Resource implications

- Cost
- Size of publications
- Complexity of documents
- Changing information
- Budget
- Staff time

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Risks

- Reputation
- Cost/timeliness
- Accuracy



Proposed translation policy

- Consider on case-by-case basis on request only
- Checklist



Evaluation

- Requests will be monitored

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Recommendations

- Consider & agree to the translation and interpretation policy
- Agree to translate or interpret only on request
- Agree that the Communications Team review the translation and interpretation policy after a year

Lunch

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Item 8

Draft Communications Strategy

David Williams

Acting Head of Communications

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Our audience

Patients

- Prospective
- Current and former
- Donor conception
- Parents
- Older women
- Same sex couples
- Single women
- Representative member groups

Donor-conceived people

Donors

- Prospective, current & former

Professionals

- Centre staff
- Professional bodies
- NHS Commissioners
- GPs / Hospital Gynaecology Units

General public

Government

- DH / other regulators
- UK Parliament
- Devolved bodies
- European Union

Our audience

Research and funding bodies

- Medical and social science
- Ethics Committees
- Medical disease charities

Comment and interest

- Pro-life groups
- Pro-science groups

International bodies

- ESHRE
- ASRM
- World Health Organisation

Media



How are we perceived?

Patients, donors and parents of donor-conceived

- Informing choice
- A central source of information for statistics and data
- Overseeing, guarding and protecting people's rights
- Creating guidelines for clinics to abide by
- Creating barriers with too many rules

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How are we perceived?

Patients, donors and parents of donor-conceived

- Not understanding everyone's needs
- Controlling funding and eligibility for treatment
- Don't see us - don't know who we are
- Where we've established good links with DC groups, the parents of donor-conceived are very aware of us

How are we perceived?

Licensed centres

- Bureaucratic
- Transparent and responsive
- Inconsistent
- Compliance seen as burdensome
- A reputation for sitting on the fence

Professional bodies

- Critical of HFEA's inconsistent decision-making
- Regulatory burden, especially, information gathering
- Good relationship with nurses and patient groups

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How are we perceived?

Researchers

- Limited awareness of the access to our data

GPs

- Limited awareness of our role
- Don't understand commissioning policies, funding arrangements and wider fertility treatment issues

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How we want to be seen

- Open, listening and constantly improving
- Decisive and not afraid to take a tough stance
- Making well-considered judgments
- Consistent in our approach
- Consulting widely on new policies

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How we want to be seen

- Not afraid to engage in debate over difficult ethical issues
- Empowering patients to make well informed decisions while creating a safe environment throughout their treatment journey
- Committed to evaluation
- Empathetic to patients, donors and the donor-conceived
- Encouraging research by allowing access to our data

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Key messages

- The HFEA has changed the way we work and continues to improve
- We are now more open and transparent in our decision making processes
- We provide accurate independent information to all our stakeholders
- We listen, monitor and evaluate to see where improvements can be made
- We are here to protect people's safety when using fertility services

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Our methods

- HFEA website and digital channels
- Publications
- The media and stakeholder channels
- Events / meetings
- Social media

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Recommendations

Members are asked to:

- agree proposed key messages
- agree proposed view on how we would like to be viewed by our stakeholders
- make any additional recommendations or amendments to the strategy

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Item 9

Donation Review

Danielle Hamm (Policy Manager)

and

Hannah Darby (Policy Manager)

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Overview

Donor codes

Conditional donation

Donation review
- early options

Upper age limit
– sperm donors

Intra family donation



Early thinking on
consultation approach



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Donor codes

- The disclosure of donor codes is not permitted under the Human Fertilisation and Embryology Act 1990 (as amended)
- The HFEA has no power to disclose donor codes to parents of donor conceived children



Recommendation (3.17):

Confirm ban on the disclosure of donor codes on a permanent basis.

Upper age limit for sperm donors

SCAAC

HFEA should not issue upper age limit; flexibility should be built into guidance as sperm quality will vary between donors.

Register data

Indicates that 19% donors between 41 and 45 years old.

Legal advice

Age restriction may be imposed if there are good medical reasons

Recommendation (4.18-4.21):

- Authority should no longer specify age limit for sperm donation
- COP should give clinics flexibility to assess donors on case by case basis
- COP should require clinics to give recipients information on increased risks of miscarriage with advanced male age
- COP should refer to RCOG recommendations on reproductive ageing

Conditional donation

Legal advice

The attachment of conditions to donations might result in a treatment centre discriminating against persons because of prohibited characteristics under the Equalities Act 2010

Consultation

Discussions with the Equalities and Human Rights Commission are ongoing

Recommendation (5.13):

- ELAC – policy should be determined by legal advice in consultation with EHRC. The Authority should not publicly consult on this issue.
- Bring policy and options paper to Authority once advice from EHRC received.

Intra family donation



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Mixing v. replacing gametes

Replacing gametes

For example, a woman uses her sister's eggs in treatment, instead of her own eggs.

Mixing gametes

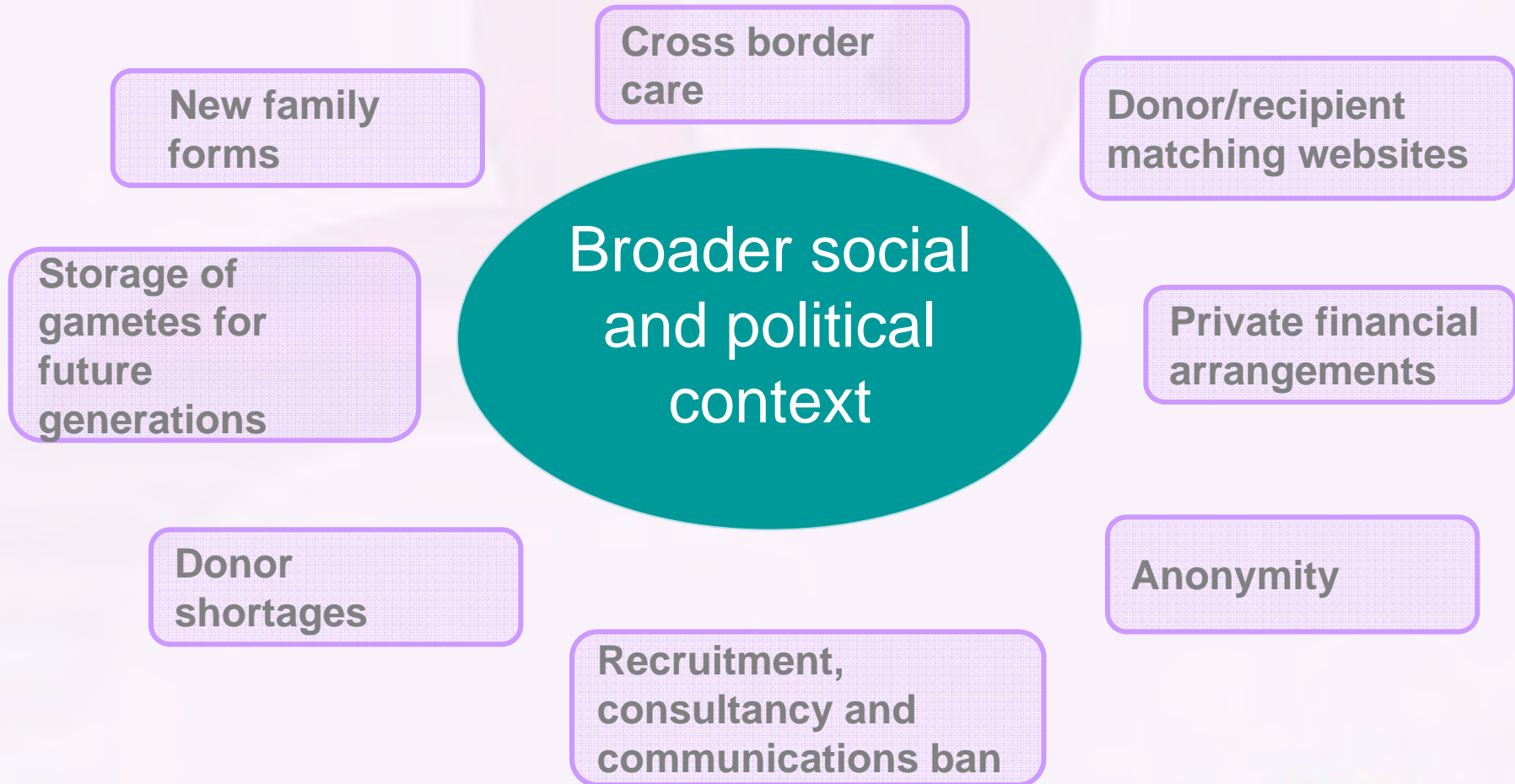
For example, a woman might be treated with her own eggs and her brother's sperm.

Consensus – some types of *mixing* of gametes should be prohibited.

Recommendation (6.37):

- Are the ethical issues identified in 6.10 the right ones to consult on?
- Is the consultation approach suggested by ELAC in 6.35 the right one?
- Are the policy approaches considered in 6.21-6.33 the right ones to consider in public consultation?

Consultation approach



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Next steps

September
2010

Compensation and Family limit –
evidence and consultation options

October
2010

Consultation approach

December
2010

Consultation paper

Jan - March
2011

Public consultation

May
2011

Authority decision

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Item 10

Update from Committee Chairs

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Item 11

A.O.B.

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Date of next meeting

Wednesday 8 September 2010

Venue: Glaziers Hall, London