

Focus on **REPRODUCTION**

European Society of Human Reproduction and Embryology

// JANUARY 2013 //

Happy families



The children conceived by assisted reproduction

- ESHRE news
- A new era for the ESHRE journals



29th Annual Meeting of the
**European Society of
Human Reproduction & Embryology**

For more information, please visit www.eshre.eu

**London, United Kingdom
7 to 10 July 2013**



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JANUARY 2013

Focus on

REPRODUCTION

● Chairman's introduction



The technical requirements of the EU Tissues and Cells Directive with respect to the frequency of viral testing (2006/17/EC implementing Directive 2004/23/EC) have finally been amended by the European Commission. The ART sector has long complained that certain requirements of the Directive were not applicable to gametes and embryos. So ESHRE's Task Force on the EUTCD has done a great job in advising the Commission. The amendment was published in the official journal of the EU on 26th November, and from now on Member States can require

testing 'at fixed time intervals which they may determine up to a maximum of 24 months instead of at the time of each donation'. The change, while maintaining the safety of ART, will lower the burden of time and cost to patients and providers. The advisory role of our EUTCD Task Force is essential to ensure that the requirements of the Directives conform to best practice in our field - and this amendment represents a first step in that direction.

Following completion of the latest terms of office, new Editors-in-Chief of our journals have been appointed. Hans Evers, Felice Petraglia and Chris Barratt will replace André Van Steirteghem, John Collins and Steve Hillier respectively. And let me here express my deep thanks for the excellent work done by André, John and Steve - as reflected in the journals' fantastic impact factors.

Five years after the first examinations for ESHRE's embryology certification, the analysis of results shows that 569 senior and 315 clinical embryologists have so far been certified. Since the last exams in Istanbul, senior embryologists from outside the EU can also apply. As you will see on page 9, the results obtained by the seniors is now relatively stable, but there is a decrease in those obtained by the clinicals - probably because of a change in the population.

The ESHRE guidelines for endometriosis are almost ready for approval by the Executive Committee and then for release. New guidelines on psychosocial care in infertility units and on premature ovarian insufficiency are also under way.

Our next annual meeting, this time in London, is already not far away. A number of attractive pre-congress courses and a full three-day scientific programme are already in place. But please note that abstracts for submission to the oral and poster programmes must follow a new format taken from the ESHRE journals. This will allow a more careful selection of the best abstracts for presentation, and ultimately a very attractive and informative meeting in London!

Anna Veiga

ESHRE Chairman 2011-2013

CONTENTS

NEWS

- 4 Time to be thinking of London
- 8 Istanbul evaluation
- 9 Five years of embryology certification
- 10 The best of ESHRE and ASRM
- 11 An app for the ESHRE journals
- 12 Poland's move towards ART legislation
- 16 From the Paramedical Group
- 17 From the Special Interest Groups

FEATURES

- 26 Hans Evers in profile
Human Reproduction's new Editor-in-Chief talks to *FoR*
- 28 What the future holds for the ESHRE journals
Online and open access the next challenges
- 30 Happy families
Susan Golombok reviews the impact of ART on parenting and child development



Time to be thinking of London



Deadline for abstract submissions is 1st February

When the founders of ESHRE include a Nobel laureate, it's a tall order to reflect that achievement in the composition of our scientific programme for London 2013. But their collective wisdom in creating special interests within ESHRE makes the task a little easier, with the foundation of a multidisciplinary approach to reproductive medicine and a 360 degree integration of science and practice. So

translating scientific breakthroughs into clinical effectiveness has been our aim and we hope that the assembled topics and speakers can maintain such a prestigious legacy.

The main scientific programme for London 2013 is now in place and it perpetuates the long-held tradition of forefront science, improved patient care and the best

The new ESHRE journal editors cast an eye over the invited programme and take their pick



Chris Barratt, *MHR*, recommends Session 6 on Monday afternoon: Regulation of sperm motility by the female tract and oocyte: messages and signals (MHR session). 'This is the one for me . . .

there are rapid and exciting developments in this area. We understand so much more than we did 12 months ago and the pace of progress is logarithmic.'

Hans Evers, *Human Reproduction*, picks session 28 on endometriosis-associated pain, on Wednesday. 'The first lecture on nerve fibres is a classic example of thinking out of the box. There seem to be nerves (why?) in the endometrium of women with endometriosis but not in those without. The second, on central mechanisms of pain, even notes morphological changes in the brain! Fascinating pictures, convincing evidence.'



Felice Petraglia, *Human Reproduction Update*: 'It is a difficult decision, but I am influenced by my own experience. So the session on pain associated with endometriosis is of great interest to me, with both diagnostic and therapeutic implications. The presentation on CNS mechanisms represents a high level of clinical translation and an advance in PCOS diagnosis.' Invited session 28, Wednesday 12:00, Endometriosis-associated pain.





The Mayor of London sends a message

Boris Johnson, the Mayor of London, has wished ESHRE well for its 29th annual meeting in London. Introducing the ExCeL centre's welcome-to-London leaflet, the Mayor - tipped by some to be the next UK Prime Minister - wrote: 'I am delighted to hear that London has been chosen for the 29th Annual Meeting of ESHRE in 2013. Our city ranks within the best in the world for international congresses and is capable of delivering events of the magnitude of ESHRE 2013.' ESHRE is one of 13 major medical congresses to be staged in London this year, in what is a substantial restoration of the city as a world congress venue.

speakers in their expert areas. So whatever your special interest in ESHRE, we hope we have the key to unlock new ideas and consolidate the basics in state-of-the-art updates and historical analysis. For those who like interaction, there are debates and of course a packed programme of abstract-based free communications.

The 15 all-day pregress courses on Sunday increasingly attract more and more participants, such that in recent years just under a third of our total delegate number has actually started their congress before the opening ceremony.

This year, whether it's fertility preservation, cryopreservation or pluripotent stem cells, or simply getting your work published in ESHRE journals, there will be a course to suit you. If you haven't given a pregress course a try, think about joining the thousands who have enjoyed them already.

And all this in what is increasingly acknowledged as the most exciting city in the world - and hosted in London's first-ever international convention centre.

The ExCeL centre - now recognised as one of London's greenest, most energy-efficient public venues - is part of the huge redevelopment programme of East London, which today includes Canary Wharf (10 minutes away and one of Europe's most important business districts), the O2 centre (also 10 minutes away and a non-stop venue for music and entertainment), Westfield Stratford (10 minutes away and the largest urban shopping centre in Europe), and of course the Queen Elizabeth Olympic Park, where last year's Olympics were sensationally staged.

But if you think you know everything else about London, think again. So first, here's what the city has to offer in numbers:

- 6000 restaurants (55 with Michelin stars)
- 40,000 shops, with chic shopping centres in Knightsbridge, Bond Street, Chelsea and Covent Garden
- 80 individual markets
- 150 theatres, with world famous venues around the Strand and Shaftesbury Avenue
- 120 historic buildings, and four World Heritage Sites
- 250 art galleries (nearly all free entry)
- 300 museums
- 70 free attractions - including the British Museum (London's top attraction), the Victoria & Albert Museum, the Natural History Museum and Tate Modern
- More than 3000 parks and open spaces
- 4000 pubs



Among a list of 120 historic buildings London boasts four World Heritage Sites - the Royal Botanic Gardens at Kew (pictured above), Greenwich (across the river from ExCeL, pictured centre, which includes a Royal park, maritime museum and the Royal Observatory, where time began), the Palace of Westminster (top right, Britain's political nerve centre), and the Tower of London (lower right, which dates back to the Norman conquest of the 11th century).

London is also a centre of excellence for education and medicine, with almost a half million students in higher education, 48 hospitals and five medical schools (all with great historical teaching traditions), and 18 medical research centres (including many of the UK's Medical Research Council).

And remember too that London is renowned as a creative capital, home to some of the world's leading talents in broadcasting, music, news and literature, and as centre of culture and diversity. Indeed, there are more languages spoken in London than in any other city of the world.

Getting around

It's big, but London needn't be intimidating.

The main link with ExCeL is via the Docklands Light Railway (DLR), with nearby stop at Custom House and Prince Regent. And the DLR is accessible from Central London via the new Jubilee Line, the only line on the London Underground with direct connections to every other line. Jubilee Line trains run every two minutes at peak times, so making connection with the ExCeL and all corners of London quick and efficient.

Or if rail links prove too dull, you might also try the

Emirates Air Line cable car, with a crossing every 30 seconds between the O2 south of the river Thames (Greenwich Peninsula) and the ExCeL centre, or the river services of Thames Clipper (which run right to the O2, with cable car connection to the ExCeL).

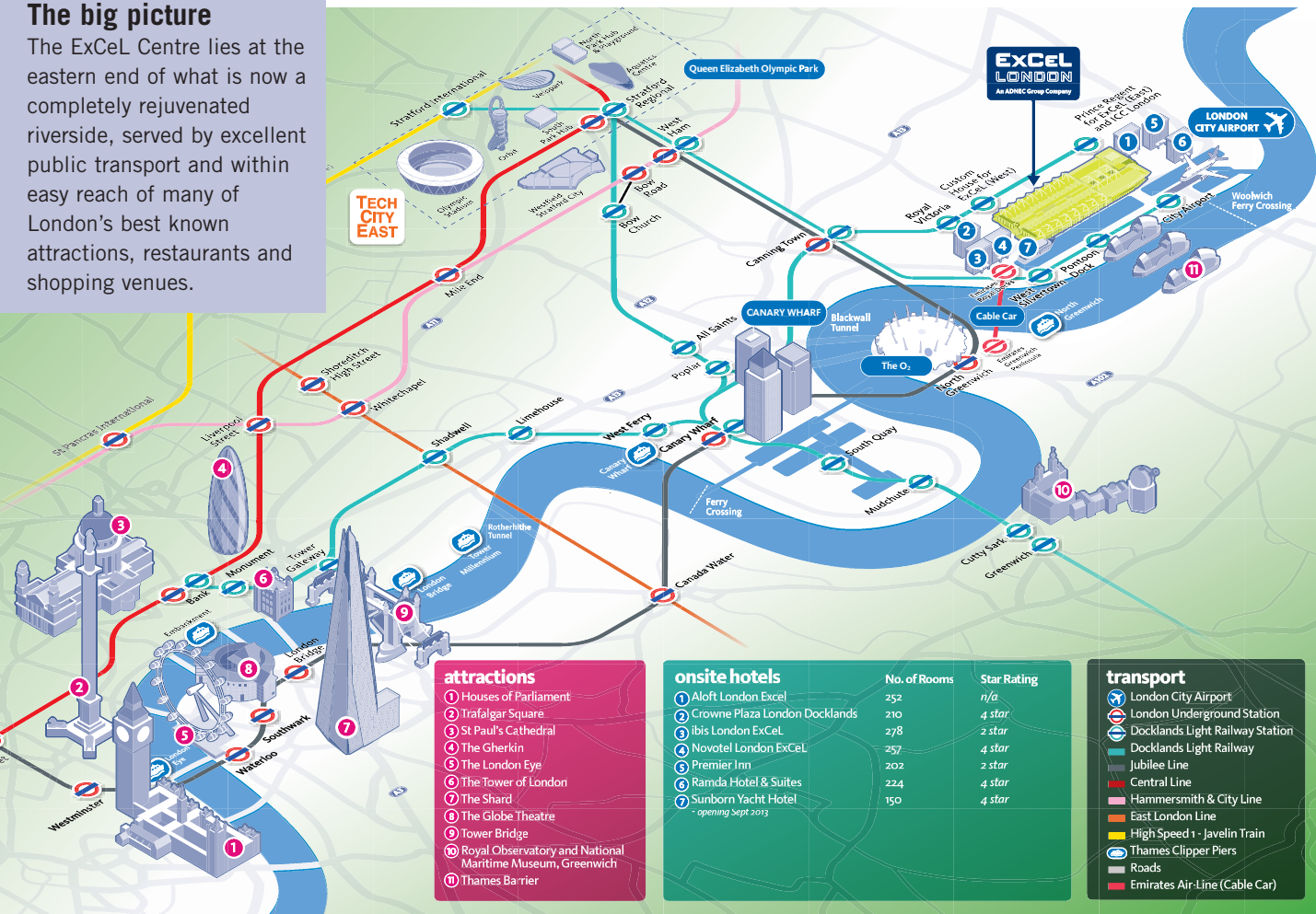
Best travel tip is to ignore the famous London taxis (great for short trips) but to use public transport for all travel to and from ExCeL. A travel Oyster card can be bought at all Underground stations or online at www.tfl.gov/visitorshop.

But today you needn't travel too far from ExCeL to find fabulous hotels, excellent restaurants and many of the sights which made London famous. Within a few minutes are Tower Bridge, Borough Market and the whole Thameside redevelopment areas around what is now



The big picture

The ExCeL Centre lies at the eastern end of what is now a completely rejuvenated riverside, served by excellent public transport and within easy reach of many of London's best known attractions, restaurants and shopping venues.





London City airport lies right by the ExCeL Centre, with daily direct flights from more than 40 European cities. Once there, the Thames Clipper river bus services operates from London Eye and Embankment piers to North Greenwich pier, for nearby cable car connection to the ExCeL.



Europe's tallest building of The Shard, or around the Tower of London and St Catherine's Dock. And in the historic City of London you'll find many hidden Victorian streets alongside fantastic modern architecture. You can find out more at www.visitlondon.com.

Getting to London

With five 'London' airports and direct high-speed rail links to Brussels and Paris, no city in the world is more easily accessible than London. And these London airports are served by direct services from 310 different towns and cities, many of them with budget airlines.

London City airport (with 350 flights a day) is just five minutes from the ExCeL by taxi and ten minutes by DLR, with speedy access to most major European cities.

Congress hotels can be booked through ESHRE's agent MCI via the ESHRE website. A hotel reservation form, with facilities to view hotels, is available.

Recent developments - and particularly last year's

A new compulsory format for 2013 abstract submissions

All abstracts intended for selection for this year's meeting must be submitted online to arrive at ESHRE no later than 1st February.

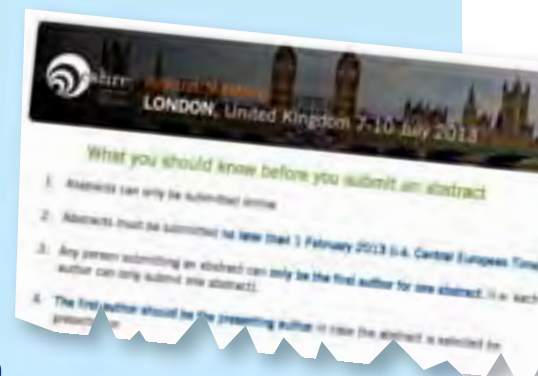
All submissions must be categorised as Basic Science or Clinical Science and identified according to a list of topics set out on the ESHRE website.¹ The substance of the abstract should be original material which has not been published or presented at any other meeting. Last year almost 1700 abstracts were submitted, of which only 248 could be accommodated in the oral programme - so competition for selection is tough.

To ensure that abstracts this year are robust and able to answer the reviewers' questions, all submissions must follow a new format (which has also been applied to abstracts for *Human Reproduction*). There are full details on the ESHRE website,² but in brief the text of the abstract should be arranged according to the following subheadings:

- Title (maximum 25 words)
- Study question (maximum 50 words)
- Summary answer (maximum 50 words)
- What is known already (maximum 75 words)
- Study design, size, duration (maximum 50 words)
- Participants/materials, setting, methods (maximum 50 words)
- Main results and the role of chance (maximum 125 words)
- Limitations, reasons for caution (maximum 50 words)
- Wider implications of the findings (maximum 75 words)
- Study funding/competing interest(s) (maximum 30 words)
- Trial registration number (maximum 20 words)

And the full abstract text must not exceed a maximum of 600 words.

1. <http://www.eshre.eu/ESHRE/page.aspx/1632>
2. http://www.eshre.eu/binarydata.aspx?type=doc&sessionId=ykmd3hamdogdygetgzdikiyuz/ESHRE_2013_abstract_submission_procedure.pdf



Olympics - have seen many new hotels built in the congress area. The ExCeL site has six hotels close by, ranging from luxury to budget, and offering 1400 rooms between them. In addition, there are over 10,000 hotel rooms within 20 minutes of ExCeL. Further afield, London is said to have 104,000 bedrooms ranging in style and budget from world famous deluxe to budget chains, bed and breakfast accommodation, guesthouses, serviced apartments and university rooms.

*Roy Farquharson, Joyce Harper,
Ertan Saridogan and Françoise Shenfield
Local Organising Committee 2013*

ANNUAL MEETING 2012

// PARTICIPANT SURVEY //

Istanbul satisfaction ratings match those of previous years

A survey of 500 participants attending last year's annual meeting in Istanbul once again found high rates of 'overall satisfaction' - with the congress venue, organisation, and scientific programme all scoring as highly as in most of the previous five years.

As usual, the interviews were conducted on site, with responses rated on a 1-to-5 mean scale (with 5.0 scoring highest), and with corresponding percentage rating.

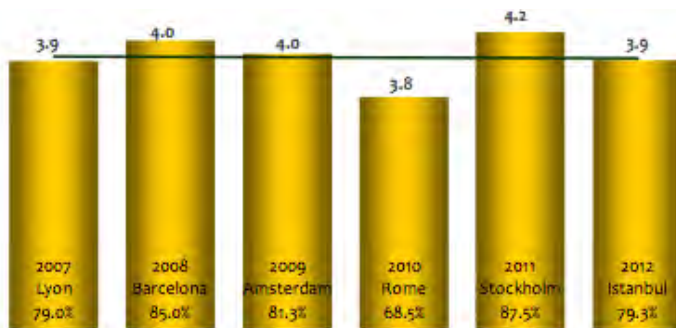
Invited Lecture sessions returned to satisfaction levels of years previous to Stockholm 2011, with a 78.0% satisfaction score and 4.0 mean. While the high satisfaction in Stockholm was exceptional, there is nevertheless a general trend showing a slight improvement.

With a 64.4% level of satisfaction and 3.8 mean, the Oral Communication sessions remain unchanged over the past five years, despite the room for improvement.

Some individual comments on both the invited and abstract sessions - as in previous years - referred to a disappointment at the lack of new material being presented. It is believed that these comments must be taken into account if the satisfaction levels are to increase. Similarly, with only half those attending the poster discussion sessions saying they were satisfied with their scientific quality (and only a 42.7% rating), many participants believed the posters can do better.

Delegates were also disappointed, as in previous years, that some of the presenters did not show up to present their work. The six year satisfaction trend for these sessions remains flat.

However, participants were pleased with the overall organisation, which received a satisfaction rating of 87.0% and a mean score of 4.1. The main points of contention were with the catering (with a low satisfaction score of



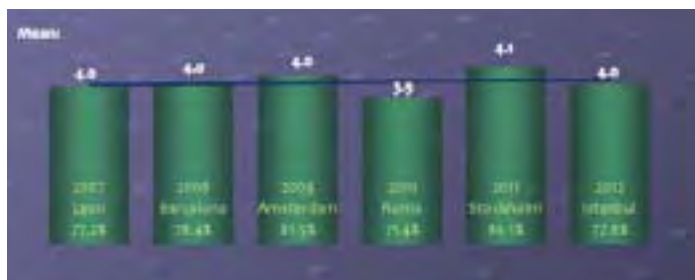
Last year's meeting received a 79.3% satisfaction and a mean score of 3.9. The six-year trend is flat with the highest ratings recorded in 2011 in Stockholm.

35.4%), and transportation (with 62.5% of satisfaction). However, more than three-quarters of respondents (78.5%) were pleased with the congress centre, which, with a mean score of 4.2, rated well above those of Amsterdam and Rome, but less than Stockholm, Barcelona and Lyon.

There was consistent agreement that information in advance of the congress was well presented, allowing them to plan their participation (81.2% satisfaction). Respondents who used the ESHRE App were very pleased with its performance

Around one-third of those present in Istanbul paid for their own registration. Employers have been able to pick up some of the slack from the decline in industry sponsored registrations since 2009. Nevertheless, almost a quarter of delegates felt the pinch of expenses when coming to the congress, saying that it was too expensive for them; 39.4% felt the cost was appropriate. It was also noted that the percentage of industry-sponsored delegates had not gone down from the previous year, despite economic and regulatory circumstances.

The survey also reaffirmed that the annual meeting continues to play a very important role in ESHRE's overall activities, as do the Campus workshops and training courses. The journals, however, are considered the most important of ESHRE 'activities' and their quality rates highly with those who have access or a subscription. Nevertheless, only around 50% of those interviewed had a journal subscription.



Invited lectures saw a return to satisfaction levels of pre-Stockholm years, with a 4.0 mean satisfaction rating.

ESHRE embryology certification: the first five years

ESHRE's embryology certification programme was launched in 2008, with the first exam for senior embryologists taking place before the annual meeting in Barcelona. However, the idea had started back in 2006 with the pioneering ideas of Arne Sunde, Søren Ziebe, Kersti Lundin and Francesca Vidal, and critical logistics support of Central Office. In the following years, both the senior and clinical embryology exams have always taken place on the Saturday afternoon before the annual meeting.

The number of European embryologists hoping to acquire this certification has continued to grow, and presently more than 870 have been certified. We believe that certification strongly contributes to the demonstration of high standards in European clinical embryology today. Moreover, the programme is now paving the way towards the formal recognition of clinical embryology on an international basis.

Indeed, one sign of the success of the certification programme is that ESHRE and the Embryology Certification Committee (EmCC) are

now being asked by other societies - in Asia and the Middle East, for example - to help set up courses and evaluation for their members. This reflects the growing importance to embryologists and IVF clinics of ways to improve and document knowledge.

Monitoring progress

The EmCC, as well as preparing the exams, continuously monitors results, suggestions and complaints, so that the whole certification process can be steadily improved.

One interesting observation is that, since the start, the senior embryologists have always had a lower success rate than the clinicals. By evaluating the specific questions of each level, as well as the questions that are common for both exams, we see that throughout the five years the seniors have performed less well than expected. One possible explanation

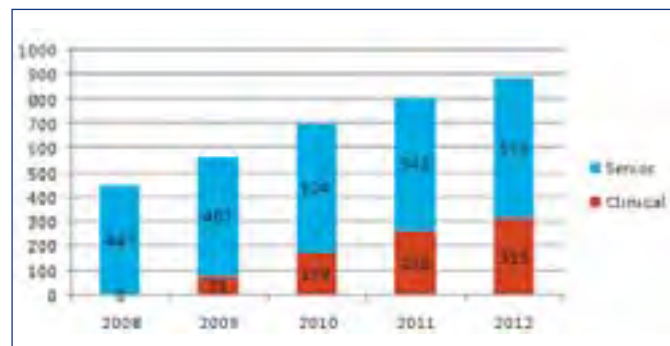
may be that these more experienced professionals are relying more on their current competence, and don't study specifically for the exam. It is important to keep in mind that the exam is a 'mark of excellence' and to pass you must have knowledge not only of clinical IVF, but of the theories of reproduction science and medicine.

The future

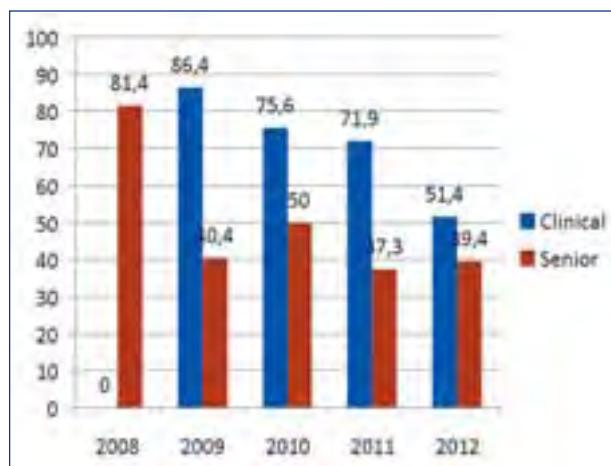
Last year in Istanbul, applications for the senior exam were also opened to embryologists working outside Europe, and we expect the number of non-European participants to increase strongly in the coming years. We hope to extend the same opportunity to non-European clinical embryologists in the near future.

In 2012 we also introduced the Continuous Embryology Education Credit (CEEC) system. So far, almost 250 senior embryologists have obtained the necessary credits to renew their certificate - about 55% of those entitled to do so. This CEEC system has now been extended to clinical embryologists as well. A system is also being developed where credits will be automatically gained from participation in ESHRE activities. However, it is important to remember that this is a voluntary activity, and there will never be loss of validity from a previously obtained ESHRE embryology certification.

Carlos E. Plancha
Co-ordinator EmCC



The number of both senior and clinical certified embryologists has steadily increased over the first five years of the scheme.



Exam success rates 2008-2012: the senior embryologists have always had a lower overall success rate than the clinicals.

ESHRE NEWS

// THE BEST OF ESHRE AND THE ASRM //

Bahamas the venue for best practice meeting

The second joint scientific programme devised on both sides of the Atlantic

The first 'best practice' meeting of ESHRE and the ASRM, held last year in the Italian ski resort of Cortina d'Ampezzo, was, according to former ASRM chairman Roger Lobo, 'an experiment' but one which proved popular, stimulating and enjoyable. This year's event, whose programme has once again been devised for both learning and socialising, will take place over three days from 7th-9th March in the sunshine resort of Paradise Island in Nassau, Bahamas.

'The meeting continues a collaboration between our societies to provide clinicians and basic scientists from around the world updates on the most current concepts in reproductive medicine and biology,' says ESHRE Chairman Anna Veiga. Subjects have been chosen for their topicality and for their relative difference in approach between Europe and the USA.

The 'best of' meetings are foreseen by both societies as annual events alternating between leisure venues in Europe and the USA and to be held during the Spring season..

Details about registration, hotel accommodation and transport can be found at <http://www.asrm.org/Atlantis2013/>.

Lectures

Back-to-back sessions, during which different topics and practices will be analysed from the American and European points of view

Debates, in which two experts will discuss controversial issues, illustrating different points of views and supporting different theories and approaches

Cutting-edge lectures, aiming to illustrate innovations and new findings in reproductive medicine and embryology

Thursday 7th March

- | | |
|-------------|--|
| 08.00-08.30 | From the NIH methodology workshop on PCOS
R. Lobo (USA) |
| 08.30-09.30 | Epigenetics and ART: embryonic and extra-embryonic effects
M. de Rycke (BE) and C. Coutifaris (USA) |
| 09.30-10.00 | The real risk of ovarian carcinoma in endometriosis
P. Vercillini (IT) |
| 10.30-11.30 | PGS: what works and what doesn't work
N Treff (USA) and J. Geraedts (NL) |
| 11.30-12.30 | Management of infertility centres
L. Gianaroli (IT) and G.D. Adamson (USA) |
| 12.30-13.00 | In vitro maturation of eggs and follicles
D. Albertini (USA) |



Friday 8th March

- | | |
|-------------|--|
| 13.00-13.30 | ICSI or not ICSI: risks of male factor infertility for ICSI
P. Devroey (BE) |
| 13.30-14.30 | Stem cells: embryonic vs adult
H. Taylor (USA) and K. Sermon (BE) |
| 14.30-15.00 | Ethics of PGD for sex selection
J. Daar (USA) |
| 15.30-16.30 | Anonymous vs non-anonymous gamete donation
G. Pennings (BE) and A. Braverman (USA) |
| 16.30-17.30 | Embryo assessment: genomics, proteomics, metabolomics
R. Reijo Pera (USA) and M. Messeguer (ES) |
| 17.30-18.00 | Gametes from stem cells
A. Veiga (ES) |

Saturday 9th March

- | | |
|-------------|--|
| 08.00-08.30 | Financial aspects of ART throughout the world
G.D. Adamson (USA) |
| 08.30-09.30 | Fertility preservation: female and male
TBA and R. Brannigan (USA) |
| 09.30-10.00 | Demographics of ART
J. de Mouzon (FR) |
| 10.30-11.30 | Robotic vs laparoscopic myomectomy
A Gargiulo (USA) and C Lönnerfors (SE) |
| 11.30-12.30 | Neo-oogenesis in the adult ovary
E. Telfer (UK) and K. Liu (SE) |
| 12.30-13.00 | Update on the molecular basis of male infertility
D. Lamb (USA) |

Download the app and read all three ESHRE journals while on the move

An app for all three ESHRE journals is now available from the iTunes store. Downloading the app provides access to both online and offline content; all archived and current issues and articles can be downloaded when you're online, and can be read later offline.

The app, which gives access to *Human Reproduction*, *Update* and *MHR*, allows you to:

- Browse content online and offline
- Easily navigate journal articles, figures, and tables
- Use the built-in search feature
- Save the most relevant articles to your favorites

The app is designed for use by iPhone and iPad.

You can read more about future plans for the ESHRE journals and a profile of the new Editor-in-Chief of *Human Reproduction* on page 26.



Download the app at
<https://itunes.apple.com/gb/app/eshre-journals/id575771559?mt=8>

ESHRE joins fellow societies in position paper on ART birth defects

In the wake of several recent papers suggesting a higher rate of birth defects in ART-conceived children than in those spontaneously conceived, ESHRE and other leading societies are now finalising a position statement expressing their consensus view. The statement draws on all evidence reported since 1980, both original studies and systematic reviews.

However, the writing group has acknowledged the difficulty of the task with respect to data interpretation - notably in an inconsistent definition of 'birth defects' - and is using the major and minor anomaly definitions of the CDC.

In 2009, drawing on data from the Nordic registries, ESHRE's SIG Safety & Quality in ART put the risk of a birth defect in ART babies at 'about 3%', adding that 'a similar increased risk has been reported for subfertile couples who get pregnant spontaneously after a prolonged time period', a risk thought mainly 'due to parental characteristics from the infertility status and not to the treatment given'.

Joining ESHRE in this latest collaborative statement is the ASRM, the International Committee Monitoring Assisted Reproductive Technologies (ICMART), the International Federation of Fertility Societies (IFFS) and the Society for Assisted Reproductive Technologies (SART). It is hoped that the final text will be available before ESHRE's annual meeting in June.

Tweet when you can from #ESHRE events



In its bid to increase the use of social media, ESHRE is encouraging the use of Twitter during workshops and meetings. So if you feel like sharing your thoughts or making comment on what's going on at an ESHRE event, your input on Twitter is welcome. You should not forget to mark your tweets with the ESHRE hashtag (#ESHRE) or send your remarks directly to ESHRE's Twitter account, which is simply @eshre.

Focus on Reproduction: online or on paper?

In general, magazines have retained their hard-copy print readership better than newspapers, books (and medical journals) - and we assume this is the case with *Focus on Reproduction*. But we're keen to know your opinion. You can let us know by answering the online survey now available on the ESHRE website. Just vote for online or on paper, and we'll have a better idea of how you prefer to read the newsletter.



Poland moves towards ART legislation with proposals for state-funded IVF

After decades of acrimonious wrangling over IVF and a continuing absence of any dedicated legislation, Poland seems now on the brink of providing some degree of state-funded IVF to infertile couples, despite political opposition. In October Poland's Prime Minister Donald Tusk, from the ruling centre-right Civic Platform party, announced plans for the public funding of IVF for couples - married and unmarried - for up to three cycles over three years provided other treatments have failed.

Not surprisingly, the move put Tusk on a collision course with his more conservative opponents, who continue to insist that IVF violates Catholic doctrine.

Two years ago, in a report on the ideological rift which IVF had driven into Polish politics, *Focus on Reproduction* found pro-IVF politicians and doctors facing huge opposition from groups backed by the Catholic church.

Yet then, as today, a large number of increasingly secular Poles appeared to back IVF, which has been performed in Poland for 25 years. Although there is no national registry, clinic data suggest that around 5000 cycles are performed each year, but so far the legislation to regulate treatment has proved too hot for Parliament to handle.

'There's an impasse in the Parliament because of the wide scale of opinions,' said Tusk at a news conference. 'This is why I thought it was important to avoid influencing what will be expected from the bill and to secure the safety of patients.'

According to *The Economist* magazine, Tusk's Civic Platform colleague Jaroslaw Gowin is himself the author of a legislative proposal which would limit IVF to married couples and ban embryo freezing - a

policy which currently seems at odds with Tusk's own.

Not every Polish clinic, however, seems disposed to legislation. *The Economist* cited some specialists who feared that regulation 'would lead to red tape and delays that could reduce the chances of getting pregnant for many women'.

Dr Ireneusz Polac, one of two Polish members of ESHRE's Committee of National Representatives, described the funding move by the Polish government as 'unexpected', adding that the proposals are for 15,000 cycles to be reimbursed over the next three years, but would not cover the cost of medication for ovarian stimulation.

'We do appreciate the decision,' he told *Focus on Reproduction*, 'but



Ireneusz Polac: 'We do appreciate the decision.'

at the same time we still believe that it is little more than a drop in the ocean, given the fact that Poland's population of 38 million people includes around 1.3 million with fertility problems. Nevertheless, as doctors dedicated to the treatment of infertility, we hope that this decision of the Polish government is a first step towards full reimbursement for all Polish couples in need of treatment.'



Poles apart

Poland is finally facing up to legislation in IVF, but not without acrimony - bitter conflicts of ideology. Simon Brown reports.

U... and events that were not their concern... in Europe with little or no regard... legislation for IVF. Ireland, Croatia, and... Poland's legal status has been clarified... professional guidelines endorsed by its health... ministry, while the Civic Platform at the end of... October did finally pass an amended law on IVF... making it easier for couples to secure treatment. The... Parliament. And only then, after... would a bill progress to become... There will be a long way to go... 2015 to see politically how the... decision for something or other... in proper place in the statute... But whether this year or next... that IVF will, in our shape of...

After sudden legislative agreement, Malta too votes for state-funded IVF

Having similarly battled the ideologies of reproduction as in Poland, Malta approved an Embryo Protection Bill - known more familiarly as the 'IVF Bill' - on 26th November last and immediately promised to roll out state-funded IVF for all. The Bill will for the first time bring regulation to ART in Malta - and thereby make reimbursement constitutionally possible.

As in Poland, IVF has been 'legal' in Malta despite an absence of legislation, but it had to be performed privately and without public funding. Recently, in debating its proposed bill, Malta appeared to have taken a more restrictive line than that reflected in the state-funding announcements in Poland, with a determination to ban embryo freezing. That argument gathered momentum in contentious claims that oocyte cryopreservation (with vitrification) was a viable alternative - a view which Parliament in approving the Bill appeared to accept, despite the opinion sought by Maltese politicians from former ESHRE Chairman Luca Gianaroli. He argued that that oocyte vitrification is an expensive procedure and will not benefit the majority of older female patients.

However, despite the expert opinion, the Bill's embryo freezing ban now looks to have been accepted by both major parties, and a conservative government approach seems to have prevailed. The provision seems to be that two fresh oocytes from each cycle can be fertilised for transfer, and the rest stored.

ASRM relaxes its 'experimental' tag for oocyte cryopreservation - though not for social reasons

Last year's annual meeting of the ASRM saw several new position statements unveiled, including an update on the cryopreservation of mature oocytes, which, says the Practice Committee, 'should no longer be considered experimental'.¹

This was a hot topic of debate during last year's 'Best of' joint meeting of ESHRE and ASRM, the latter doggedly defending the experimental corner. But the latest ASRM opinion, while acknowledging that 'IVF practices in Europe differ considerably from those in the United States', now finds sufficient evidence to recommend oocyte cryopreservation for fertility preservation ahead of cancer treatment but not yet for donor egg banking, social reasons, or in lieu of embryo cryopreservation. The latest position paper from ESHRE's SIG Ethics & Law on age-related fertility loss found the arguments against social oocyte freezing 'not convincing'.²

The ASRM also remains firmly opposed to any strict limitation (as defined by law, for example) on the number of embryos to be transferred in an ART cycle. 'Transferring greater or fewer embryos than dictated by these criteria may be justified according to individual clinical conditions, including patient age, embryo quality, the opportunity for cryopreservation, and as clinical experience with newer techniques accumulates,' says the

ASRM in its revised criteria on the number of embryos for transfer.³ However, the ASRM continues to emphasise that 'the goal of ART is to achieve a singleton gestation'.

The revised recommendations, in the light of SART data available up to 2010, are as in the box below.

1. The Practice Committees of the American Society for Reproductive Medicine and the Society for Assisted Reproductive Technology. Mature oocyte cryopreservation: a guideline. *Fertil Steril* 2012; doi:10.1016/j.fertnstert.2012.09.028
2. ESHRE Task Force on Ethics and Law. Oocyte cryopreservation for age-related fertility loss. *Hum Reprod* 2012; 27: 1231-1237.
3. The Practice Committees of the American Society for Reproductive Medicine and the Society for Assisted Reproductive Technology. Criteria for number of embryos to transfer: a committee opinion. *Fertil Steril* 2012; doi:10.1016/j.fertnstert.2012.09.038

Prognosis	<35 years	35-37	38-40	41-42
Cleavage-stage embryos				
Favourable	1-2	2	3	5
All others	2	3	4	5
Blastocysts				
Favourable	1	2	2	3
All others	2	2	3	3

* Favourable = first cycle of IVF, good embryo quality, excess embryos available for cryopreservation, or previous successful IVF cycle

Ethnic minority in India adopts IVF as a population policy



Parsi girls at the Parsi Agiary (Fire Temple) at Mumbai, India

In the face of dwindling numbers and possible extinction, the Parsi communities in India have been granted permission and funding to set up clinics for fertility treatment - in what may well be the first time that IVF has ever been formally adopted as a population measure.

A census in 1940 put the Indian Parsi population at around 110,000 but the 2001 census counted only 60,000, with no more than 200 births per year recorded. Late marriages and migration were considered the main explanations, although the Parsi culture excludes children born to Parsi women and non-Parsi fathers. Some 30% of Parsi women are reported to be unmarried.

According to reports in the Indian press, the Government will now bear the cost of fertility treatment for Parsi community members, who are concentrated mostly in Mumbai, Gujarat and Kolkata.

The present-day Parsis of the Indian sub-continent are said to have descended from the followers of Zoroastra in Persia and emigrated to India during the 10th century AD to avoid persecution from invaders.

Regulation, audit, certification and quality management in the European IVF centre

Better results, greater efficiency and improved patient satisfaction

For most IVF clinics in Europe the concepts of inspection and certification are relatively new. Indeed, in 2004, when it suddenly dawned on the IVF community that their practice would be included in a new EU directive on tissue and cells for human application, the thought of inspections and 'compliance' filled them with dread.

But today regulation and a benchmark of standards have now become the norm. Indeed, in the UK inspections have been part of the HFEA's licensing process for the past 20 years, and guidelines in ART - on good laboratory practice from ESHRE or on minimum clinical standards from the ASRM - have been common currency throughout the past decade. ESHRE itself introduced its own embryology certification scheme in 2008 and since then has seen the numbers of enquiries and qualifiers rise beyond all expectations.

So it was no surprise that a show of hands from more than 80 participants at an ESHRE Campus meeting on standards and quality in IVF found that almost all were now working in establishments with ISO 9001 certification for quality management systems, nearly all gained within the past ten years. Such certification, said former ESHRE chairman Basil Tarlatzis opening the meeting, would bring benefits not just to the processes of management and patient satisfaction, but also to a clinic's efficiency and results.

The meeting - held in September - was jointly organised by ESHRE's SIG Safety & Quality in ART and



Course organisers Edgar Mocanu, Co-ordinator of ESHRE's EUTCD Task Force, and Petra De Sutter, Co-ordinator of the SIG Safety & Quality in ART

EUTCD Task Force and attracted a large audience of embryologists, quality assurance managers and even a sprinkling of regulators.

The overall impression from the meeting was that regulation, audit and inspection were nothing to be feared, and indeed would - as Tarlatzis proposed - bring benefit to the clinic and its patients. Swedish embryologist Kersti Lundin, in speaking specifically of the EUTCD, said that its requirements had already brought 'increased awareness on quality, procedures, training and education'.

There were, however, still several 'problem areas' in the 'technical' directives (2006/17/EC and 2006/86/EC) which, she said, were 'a consequence of the broad coverage of the directive in comparison to the very specific nature of ART'. These problems related to:

- Staff, being available in sufficient numbers and adequately trained; although in the lab this has been somewhat addressed by ESHRE's embryology certification programme, by which the theoretical competence of laboratory staff now has a common platform.
- Air quality, which is 'generally required' with high grade particle and microbial colony counts as defined in the current European Guide to Good Manufacturing Practice (GMP), unless exceptions apply; these, said Lundin, remain demanding requirements, even though no case of infectious disease transmission has ever been reported as attributed to air quality in the lab.
- Viral screening, which was originally required in all donors 'at the time of donation' and implied, said Lundin, that a new test should be performed with each cycle of

treatment, even when the 'donors' are husband and wife and at no risk of viral disease.

As reported in September's issue of *Focus on Reproduction*, this anomaly seems now to have been addressed, with news that the EUTCD's regulatory committee and Member State competent authorities have agreed to a revision of the guideline such that 'testing at fixed time intervals up to a maximum of 24 months', and not at the time of each donation, is a 'more proportionate' approach.

The amendment requires Member States to legally enact the changes before 17th June 2014 at the latest, by when the amended text, with reference to the Directive, must be incorporated into national law. Given ESHRE's role in providing the evidence in favour of a more relaxed approach, this was, said Lundin, 'a huge success'.

On the more everyday question of quality and safety in the IVF laboratory, Belgian embryologist Etienne Van den Abbeel identified three areas currently critical for consideration: culture systems and the embryo's development in culture; embryo selection; and cryopreservation. Most contentious is the composition of culture media for ART, where debate remains concentrated on sequential versus monoculture systems, and on the role of each ingredient, not least certain growth factors and amino acids.

There is, said Van Den Abbeel, still no strong evidence to resolve these concerns - no randomised trial on which culture medium or system is in the embryo's best interest, and no disclosure from manufacturers on the exact composition of their media.

The traceability of gametes and embryos (as well as the products and materials with which they are in contact) was a requirement of the Directives, which also stated that any serious adverse reactions and events should be notified to the competent authority. However, as Edgar



More than 80 registrants took part in the meeting, with afternoon sessions divided into practical workshops on the EU Tissue and Cell Directives.



Mocanu explained, even the Commission recognised that a harmonised system could never work without consistency in terminology or in the understanding of what a serious adverse event or reaction actually was.

To this end, Mocanu, who is co-ordinator of ESHRE's EUTCD Task Force, explained that the EU-supported SOHO V and S (Vigilance and Surveillance of Substances of Human Origin) group had developed a guidance report specifically on ART aiming to provide each Member State with a comprehensive system of surveillance, vigilance and adverse event reporting in ART. The report, which made detailed reference to the mix-up of gametes and embryos and

to their traceability, also covered terminology and safety, with sections on OHSS and procurement. The 45-page guidance, to which ESHRE was a substantial contributor, was submitted to the European Commission more than a year ago, but so far, said Mocanu, there has been no response. According to the SOHO project, 'the guidance is now a chapter in Deliverable 8 of work package 7 which will be recommended to the European Commission for application across the EU'.¹

However, this stimulating meeting made it clear that safety in the clinic and lab was not just dependent on regulation. Petra De Sutter, the co-ordinator of ESHRE's SIG Safety and Quality, and others made it clear that good practice rose above the standards of regulation, and that many of the 'risks' run by ART patients are actually risks from the treatment itself. Ovarian stimulation (OHSS, oncogenesis), oocyte retrieval (bleeding, infection), embryo transfer (multiple pregnancies) and even pregnancy itself (ectopic) all posed risks which were usually avoidable.

Not least of these was the risk of OHSS. With evidence mounting from the efficacy of freeze-all and agonist-triggering strategies, both De Sutter and Françoise Shenfield, the legally qualified chairman of ESHRE's SIG subcommittee, suggested that OHSS is rapidly becoming an unnecessary risk of ART - and, in non-patient egg donors, an event so unethical that it is now entering the range of malpractice.

1. See <http://www.sohovs.org/soho/mod/resource/view.php?id=41>

Commission confirms EUTCD virology changes

The European Commission formally adopted amendments to EUTCD viral screening requirements on 26th November, having agreed to the measures in June. The original Directive had stipulated that testing had to be done 'at the time of each donation both for partner . . . and for non-partner donation'. Now, the Commission has agreed that 'testing at fixed time intervals up to a maximum of 24 months', and not at the time of each donation, is a 'more proportionate' approach.

Formal nurse certification proposed

ESHRE sets up working group to investigate feasibility

Nurse certification and future training

With recognition that the progress of ART depends more and more on a multidisciplinary approach, with special training for all team members, ESHRE's Executive Committee has agreed to investigate a nurse certification programme comparable to that available to clinical embryologists. Our arguments are that:

- The basic training course is a good start but the Paramedical Group would prefer to see a more formal recognition, with certification for ART nurses run by ESHRE in a way similar to that available to embryologists.
- One of the aims of ESHRE is to promote improvements in clinical practice through teaching, training and continuing medical education activities for all members.

The Executive Committee has thus asked a working group comprising Helle Bendsten, Jolienke Schoonenberg, Eline Dancet, Inge Rose Jorgensen and Helen Kendrew, to consider the feasibility and practicality of an ESHRE nurse certification scheme.

Our mission is thus to promote a certification programme which acknowledges and verifies the knowledge and training of our group members in a scheme which demonstrates nursing competence compatible with the best treatment of our patients.

We are also keen to collaborate and exchange knowledge with other SIGs. Joint workshops, for example, give us the opportunity to expand knowledge to subjects outside the paramedic's main areas of interest. We feel it is also important to be recognised as equal partners in training initiatives, to co-organise Campus and pregress courses.

So now, after four successful basic training courses (held in Manchester, Valencia, Berlin and Copenhagen) and two advanced training courses (Kiev and St. Petersburg) we believe there is a need for a co-ordinated education strategy for basic training

among all members of ESHRE.

We also think there is an increasing need for high-quality basic training outside the EU. Collaboration with ESHRE's Task Forces Developing Countries and Infertility, for example, may well be a worthwhile idea. We are keen to contribute to IVF in low resource countries. This too could be done in a practical way, with hands-on sessions.

We also plan to update the ESHRE Paramedical website with, for example, regular references to papers of interest to our group. And also plan to invite sponsors and exhibitors to our Campus courses.

Events for 2013

- **Bringing evidence-based innovations to your clinic**, a Campus symposium in Leuven, Belgium, on 7-8th February. The course, organised by the Paramedical Group and SIG Safety and Quality in ART, aims to increase evidence-based practice in fertility clinics with an emphasis on
 - Patient-centeredness in your clinic
 - Innovations introduced in the IVF laboratory
 - Evidence-based tools to improve psychosocial care
 - Evidence-based medical introductions

- **Fertility preservation - the next frontier** is our pregress course in London this year. This is an advanced course for nurses and lab technicians considering a wide range of hot topics in fertility preservation. The course will cover fertility preservation in women affected by malignant diseases and those at risk of premature ovarian failure. There will also be a hands-on session with vitrification devices for oocyte cryopreservation. The ethical issues of social freezing, counselling for social freezing, oocyte cryopreservation and oocyte banking will also be discussed.

*Helle Bendtsen
Chair Paramedical Board*

The Paramedical Board 2013



This year's Paramedical Board, pictured above, comprises Eline Dancet, Yves Guns, Inge Rose Jorgensen, Helen Kendrew (Chair Elect), Ushi Van den Broek, Cecilia Westin, Leonie Van Den Hoven, Jolienke Schoonenberg-Pomper (Past Chair) and Helle Bendtsen (Chair).

SPECIAL INTEREST GROUPS

// EARLY PREGNANCY //

Winter symposium on evidence-based care

Winter Campus Course Amsterdam

Our Winter Campus course on **Evidence based early pregnancy care** was held in Amsterdam in November. The course was well attended, with challenging themes and discussion. William Kutteh, for example, proposed that the definition of recurrent miscarriage should not be limited to three miscarriages since the relative contribution of underlying factors was equally present in couples with two and three. Ioannis Gallos presented a meta-analysis showing that a single progesterone measurement for women presenting with bleeding or pain and inconclusive ultrasound assessments in early pregnancy can discriminate between a viable and non-viable pregnancy.

Results from the European Surgery in Ectopic Pregnancy (ESEP) study were presented by its co-ordinator Femke Mol. This is a large international randomised trial showing that salpingotomy did not improve the chance of an ongoing pregnancy when compared with salpingectomy in women with an ectopic pregnancy and a normal contralateral tube.

The young scientist session proved an excellent forum for speakers whose abstract was selected for oral presentation. Topics were the validation of an ultrasound based scoring system, heparin for assisted reproduction, a study protocol of early enteral tube

feeding for hyperemesis gravidarum, and a systematic review of biomarkers for nausea and vomiting in

Steering committee

Mariette Goddijn (NL), Co-ordinator
Siobhan Quenby (GB), Deputy Co-ordinator
Nick Bersinger (CH), Deputy Co-ordinator
Robbert van Oppenraaij (NL), Junior Deputy
Ole B Christiansen (DK), Past Co-ordinator



The SIG EP steering committee; from left to right, Mariette Goddijn, Siobhan Quenby, Ole B Christiansen and Robbert van Oppenraaij.

pregnancy. In a lively debate on improving recruitment for RCTs it was proposed that non-evidence based treatments should be ignored and that RCTs should be nested within daily clinical care.

The round table sessions discussed the daily clinical challenges of tubal and non-tubal ectopic pregnancy, recurrent miscarriage cases, and recruitment for RCTs. An on-site visit to the Amsterdam Early Pregnancy Unit was also part of the programme.

So we now have a good idea of what evidence-based early pregnancy care is. The next step will be to move forward with research projects to fill the evidence gaps.

Future activities

Our pre-congress course in London is titled **Risk factors for recurrent pregnancy loss – more pieces of the puzzle**, and will focus on pregnancies of unknown location, thyroid abnormalities in early pregnancy, social and lifestyle factors and their impact on early pregnancy, as well a review of the latest NICE guidelines. During the main scientific programme there will be an invited session on Monday on **Gathering evidence in early pregnancy research- making trials happen**.

A joint Campus meeting in Brussels on 28-29th November will be organised by the SIG EP and Task Force Basic Science <http://www.eshre.eu/ESHRE/page.aspx/1632in> Reproductive Medicine. The central theme - **From early pregnancy to later in life** - is the concept of developmental origins of health and disease. Topics to be covered are early implantation, prediction of pregnancy outcome by biomarkers, clinical evidence in early pregnancy, and effects from preconception and early pregnancy to later in life. The SIGEP writing team will focus on terminology and definitions of early pregnancy events in collaboration with the early pregnancy working group the ASRM.

*Mariette Goddijn
Co-ordinator SIG Early Pregnancy*



Round table sessions (above) and debates were features of November's Winter Campus course in Amsterdam.



SPECIAL INTEREST GROUPS

// STEM CELLS //

Muddled thinking and inconsistency threaten EU funding for stem cell research

Horizon 2020 and funding for human embryonic stem cells?

Institutions are currently negotiating the European Commission's new 'Horizon 2020' proposal which will set the rules for EU research funding for the rest of the decade.

As in previous programmes, Horizon 2020 raises ethical issues, including EU funding for hESC. During negotiations for the seventh framework programme in 2006, the EU cut the scope of the stem cell work eligible for EU funding - for example, excluding funding for the creation of new hESC lines or embryos for research, including those generated by nuclear somatic cell transfer. Now, the Commission has advised that the same restrictive rules should apply for hESC research in Horizon 2020.

However, although the majority at the Council of Ministers agree with the Commission's advice, some members have called for a restriction of funding to adult stem cells - and thus effectively for a total ban on hESC research. Parliamentary committees have also called for an end of hESC research funding. To top it all, the ruling of the Court of Justice of the European Union of 18 October 2011 (which, as reported in *Focus on Reproduction* in January 2012, excluded an invention from patentability in which the implementation of the process requires either the prior destruction of human embryos or their prior use as base material) is now used as an argument by the Legal Affairs Committee to completely exclude hESC research from EU funding. The Legal Affairs Committee argued that, since hESC research was

unpatentable in Europe, it could not contribute to European competitiveness and should not be funded by Horizon 2020.

The latest development in this unhappy saga is that four MEPs from Germany, Slovakia and Poland announced on 12th September that they will challenge the

legality of Horizon 2020 if stem cell funding is approved.

It is also worrying to hear that several religious organisations and Member States are also asking for a stop on EU funding for hESC research. The Commission of Bishops' Conferences of the EU (COMECE), for example, a powerful pressure group regularly consulted by the Commission on ethical matters, has already succeeded in making sure that Horizon 2020 contains all the restrictions that were present in the seventh framework programme. Even the development of iPSC technology and the latest Nobel Prize for its inventor, Professor Yamanaka, have been proposed as an argument that hESC research will soon be redundant and unnecessary.

In addition, religious concepts of human dignity and an exaggerated warning of the precautionary principle have been increasingly used to impede scientific development. The EU Court of Justice ruling of 2011 granted human dignity to 6-8 cell embryos but at the same time ignored the human dignity of patients with crippling disease, a judgement apparently inspired by a certain religious group.

Such a view is also at odds with the European Convention on Human Rights, which protects freedom of religion and freedom from religion, and with the European Charter of Fundamental Rights, which guarantees everyone the right of access to preventive health care and the right to benefit from medical treatment.

We, as scientists working in the field, and ESHRE as a body of scientists with an interest in human embryo and embryonic stem cell research, must keep a close eye on these developments and let our voice be heard to ensure the future of our research and all the benefits this research could bring for our patients.

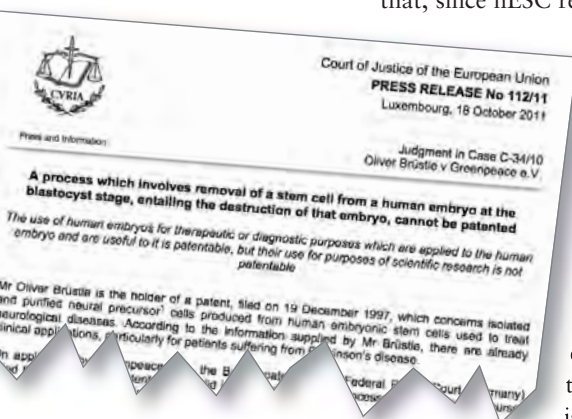
There's more reading on this at:

* <http://blogs.nature.com/news/2012/09/clouds-gather-over-european-stem-cell-funding.html>

* <http://eutopialaw.com/2012/10/24/horizon-2020-eu-funding-of-hesc-research-in-the-balance/>



Horizon 2020 is the EU's new programme for research and innovation and part of the drive to create new growth and jobs in Europe. The programme will combine all research and innovation funding currently provided through the Framework Programmes for Research and Technical Development.



How the EU's Court of Justice announced in 2011 the 'unpatentability' of processes involving the removal of stem cells from human embryos. The definition of 'human embryos' has recently been challenged in the German courts, although there the patent ban remains in place if human embryos have been destroyed.

Fertile results from andrology and embryology

The best sperm for the best oocyte

Our Campus meeting in Athens in October organised with the SIG Embryology was one of the best attended events we have held in recent years. We had 143 registrations and actually made a significant profit. However, the most abiding memory will be the content of the meeting itself and the enthusiasm of the audience - for this was a meeting which members really wanted. And members of both SIGs clearly learned much from their colleagues. The andrologists came with a view that the sperm was very important, but they began to learn from the embryologists about the importance of the egg and embryo - and the same understanding came from SIGE members as they listened to the andrologists.

The point was clearly made that, while we have a limited number of eggs and embryos, we have very large numbers of sperm, but presently no routine tests to tell the good sperm from the bad. Even the great advances in choosing the best embryos will be limited if we cannot provide the egg with the best sperm to create the best embryo. We concluded that the next 'big' advance for those working in fertility must include ways of assessing sperm parameters that impact on ART

Steering committee

Sheena Lewis (UK), Coordinator
Willem Ombet (BE), Deputy
Stefan Schlatt (DE), Deputy
Charlotte Heavisides (UK), Junior Deputy
Roelof Menkveld (ZA) Past Coordinator



Taking a break. Organisers of the Athens workshop, Stamatis Papaharitou, Sheena Lewis, Michael Pelekanos and Kersti Lundin.

outcomes.

Our local organisers, Stamatis Papaharitou and Michael Pelekanos did not disappoint us. Their attention to detail in the organisation of the event was excellent, with a marvellous social programme.

Annual meeting London

SIG members have much to look forward to in London this year. Our pre-congress course, **Is male fertility decreasing? The latest news suggests not...** will take the form of two debates, the first on whether male reproductive health is in decline, with contributions

from Niels Skakkebaek and Richard Sharpe, and the second on whether ART can be part of the solution to Europe's demographic demise. Among the speakers in the latter will be Anja Pinborg with the latest data from Denmark on ART children born from infertile fathers.

Our goal in London is that the debates will be informative but entertaining. With some of the world's leading speakers scheduled to speak on these most controversial subjects, we hope that they will provide a highlight of the meeting.

Sheena Lewis
Co-ordinator SIG Andrology

* http://www.bionews.org.uk/page_190087.asp
<http://www.wellcome.ac.uk/news/media-office/press-releases/2012/wtvm055497.html>

* <http://humanistfederation.eu/keep-dogma-out-of-european-research/>

Upcoming SIG activities

After our successful hands-on courses in Valencia and Barcelona, a third renowned centre working on human embryonic stem cells will host a further hands-on course on **Feeder-free derivation and culture of pluripotent stem cells**. We are indeed very happy that the prestigious Karolinska University Hospital and Outi Hovatta have agreed to organise the course. Their large team of scientists, reinforced by international members, have been

placed at the disposal of participants in an intensive course limited to ten participants. The four-day hands-on course will be preceded by a one-day basic **Update on pluripotent stem cells** (hESC and iPS), open to all.

In London we will hold a joint pre-congress course with the Task Force Fertility Preservation in Severe Diseases. This advanced course will try to unravel the link between pluripotent stem cells and cancer, and how this has repercussions for fertility preservation. The course will cover our current knowledge on stem cells in gonads, how these stem cells are related to cancer of reproductive organs, and how this affects both cancer and infertility treatment.

Karen Sermon
Co-ordinator SIG Stem Cells

SPECIAL INTEREST GROUPS

// REPRODUCTIVE ENDOCRINOLOGY //

Antagonist protocols underpinned by strong data

GnRH antagonist workshop

The introduction of GnRH antagonists in ART has altered significantly our approach to ovarian stimulation, particularly with regard to its conduct and safety, and to the patient's treatment burden. The availability of GnRH antagonists for suppressing the premature LH surge has thus generated enormous interest, not least because the vast majority of IVF patients are still exposed to a protocol of ovarian stimulation with issues of distress and safety two weeks before oocyte pick-up.

In December 2004, five years after the introduction of the antagonists into routine practice, the SIG RE organised a consensus workshop in Brussels from which a frequently cited report, published in *Human Reproduction* in 2006, originated. Meanwhile, a large number of studies on ovarian stimulation with antagonists, including several systematic reviews and meta-analyses, were reported, and it was thus high time to comprehensively review these developments while highlighting future directions for the clinical researcher. Many faculty members from the 2004 event were around again at the workshop, which was held in September in Hamburg, to present the latest data and and share their thoughts with a highly interactive audience.

While the conclusion of 2004 on OHSS reduction was that 'the effects of GnRH antagonist co-treatment on the incidence of ovarian hyperstimulation syndrome remains uncertain', all participants in 2012 agreed on the basis of a large number of solid RCTs that antagonist co-treatment drastically reduces the risk of severe OHSS, as both Mohamed Aboulghar (EG) and Efstratios Kolibianakis (GR) pointed out after a short introduction on the history of antagonist development (Klaus Diedrich DE).

A full session was devoted to new concepts in ovarian stimulation: Nick Macklon (GB) gave a visionary talk on

Steering committee

Georg Griesinger (DE), Co-ordinator
Frank Broekmans (NL), Deputy
Efstratios Kolibianakis (GR), Deputy
Adam Balen (GB), Past Co-ordinator
Daniela Romualdi (IT), Junior Deputy

the potential association of ovarian stimulation and adverse outcomes and shared his latest data on the embryo-endometrium cross-talk in IVF. Peter Humaidan (DK) summarised the exciting promise that agonist triggering holds for replacing hCG as the signal for final oocyte

maturation, and Paul Devroey (BE), one of the key players in antagonist research in the last 15 years, advocated the concept of segmentation in IVF treatment - that is, temporally splitting the phase of stimulation from embryo transfer and early pregnancy.

Further lectures dealt with the endogenous hormones during stimulation (Human Fatemi, BE), endometrial receptivity (Claire Bourgain, BE), the gonadotropin regimen in antagonist protocols (Basil Tarlatzis, GR) and treatment scheduling (Georg Griesinger, DE). Finally, Cornelius Lambalk from Amsterdam spoke on the place of GnRH antagonists in the context of IUI and Frank Broekmans (NL) tackled the question of how to predict response to stimulation in antagonist protocols.

During the course of the workshop it became clear how much progress has really been achieved by applying evidence-based measures to clinical research in ovarian stimulation. With around 100 participants in the audience, this workshop provided an ideal sized forum for interaction and debate between audience and faculty. The day after the meeting the SIG Deputies and Co-ordinator started to draft the outline of a comprehensive review manuscript. If everything works according to plan, we will produce a review paper from both our workshops in 2012 - on AMH (in Lille) and on antagonist stimulation, making the content widely available.

Events in 2013

- Precongress course London: **Ovarian stimulation for ART: how to achieve efficacy and safety?**
 - **Primary ovarian insufficiency – POI: Update and guideline presentation** in Utrecht, the Netherlands, as a joint workshop with the SIG Psychology. Tentative dates are 22-23rd November or 6-7th December.
 - **Polycystic ovary syndrome: A new look at an old subject** in Rome with local organiser Daniela Romualdi, tentatively 25-26th October.

Georg Griesinger
Co-ordinator SIG Reproductive
Endocrinology

Faculty of the GnRH antagonist workshop. From left to right back, Daniela Romualdi, Klaus Diedrich, Basil Tarlatzis, Nils Lambalk, Efstratios Kolibianakis, Frank Broekmans, Nick Macklon, Peter Humaidan, Claire Bourgain; front row, Mohamed Aboulghar, Paul Devroey, Human Fatemi, Georg Griesinger



Groups from ESHRE and FIGO in joint session

The SIG Ethics & Law took part in a first joint session of ESHRE and FIGO (International Federation of Gynecology and Obstetrics) at the latter's congress in Rome last October. There

was a full programme with a diversity of topics and interesting discussion. Presentations were delivered by members of the two committees, with Françoise Shenfield acting as a member of both. Shenfield also presented the work of ESHRE's

Task Force on Cross Border Reproductive Care, concluding that the principles set out in its *Good Practice Guide* are very much in agreement with FIGO's recommendations. A clear area of concern, about which more data are needed, is the impact of cross-border treatments in low resource countries on the provision of essential reproductive health services to the local population.

Duru Shah, Professor of Obstetrics and Gynaecology in Mumbai and member of FIGO's Ethics Committee, spoke about 'ethical issues of iatrogenic infertility', focusing on the cryopreservation of reproductive tissue and cells for women and men prior to cancer treatment. In this context she also discussed the ethical pros and cons of fertility preservation for non-medical reasons. Mrs Shah stressed the importance of consistent ethical and legal standards based on the cooperation of professional organisations, policy makers and patient representatives.

Bernard Dickens, Professor of Health Law at the University of Toronto, Canada, and chair of FIGO's ethics committee, stressed the ethical and legal importance of the concept of 'protection of conscience'. While this allows individual practitioners to claim conscientious objection to carrying out a specific medical procedure, this is a human right that as such cannot be claimed by institutions such as hospitals. For instance, protection of conscience cannot be invoked by the board of Roman Catholic hospitals not wanting to have abortions performed in their

Steering committee

Wybo Dondorp (NL), Co-ordinator
Guido Pennings (BE), Deputy Co-ordinator
Veerle Provoost (BE), Junior Deputy
Guido De Wert (NL), Past Co-ordinator



Speakes at the joint ethics session of ESHRE and FIGO. From left, Bernard Dickens, Wybo Dondorp, Françoise Shenfield, Duru Shah and Guido De Wert

institution. Moreover, as underlined in FIGO's 'Ethics Statement on Conscience', individual practitioners also have a right of 'conscientious commitment': the right to

undertake (or refer to others who would undertake) medical procedures according to their personal conscience.

Guido De Wert, Professor of Biomedical Ethics at Maastricht University and past chair of ESHRE's Task Force on Ethics & Law, gave a sketch of

challenging ethical questions arising in the no longer science fictional scenario of routine testing of IVF embryos with next generation sequencing technologies. An alternative approach of preconception testing of IVF couples followed by targeted testing of embryos may avoid some of these challenges, but should not be regarded as ethically non-problematic. What should the scope of such preconception testing be? And how to present the next step of targeted embryo testing: as fully non-committal, or should this take the form of a 'coercive offer'?

Finally, Wybo Dondorp, also from the ethics department in Maastricht and chair of the SIG, spoke about ethical issues arising from the introduction of non-invasive prenatal testing (NIPT) in low-risk pregnancies. Three scenarios were distinguished: NIPT as an alternative first-line aneuploidy screening test (imminent), as a one-step diagnostic procedure for fetal aneuploidy (future), or as a one-step procedure enabling testing for a wider range of genetic conditions that women may want to be timely informed about (further in the future). In addition to specific questions related to each of these scenarios, a main challenge for society will be to rethink what tests to offer in pregnancy, and why.

The next joint session of the ethics committees of the two organisations is planned to be held at the annual conference of ESHRE in Munich 2014.

Wybo Dondorp
Co-ordinator SIG Ethics & Law

SPECIAL INTEREST GROUPS

// REPRODUCTIVE GENETICS //

Webinar initiatives in reproductive genetics

We had a productive business meeting in Istanbul. Ursula Eichenlaub-Ritter agreed to take over as Co-ordinator of the SIG when Joyce's term concludes at this year's annual meeting in London.

The SIG and PGD Consortium are taking a leading role in e-learning and have already run a trial (see PGD Consortium report below), and aim to hold a number of webinars which will include standard basic lectures and interactive sessions.

Future plans

In 2013/2014 we hope to develop a number of Campus workshops. Milan Macek and Katerina Vesela are developing an exciting programme for a workshop on **Emerging technologies in PGD and prenatal diagnosis**, which will encourage human geneticists, clinicians, embryologists, scientists and experts working in PGD and prenatal diagnosis to share their experience of such new technologies as array CGH and SNP arrays. Also discussed will be developing technologies, such as sequencing.

It has also been proposed to develop a workshop in Brussels on stem cells, epigenetic and genetic stability and prospects for fertility preservation. This workshop is being

Steering committee

Joyce Harper (GB), Co-ordinator
Claudia Spits (BE), Deputy
Ursula Eichenlaub-Ritter (DE), Deputy
Tania Milachich (BG), Junior Deputy
Stéphane Viville (FR), Past Co-ordinator

developed by Ursula, Stéphane Viville, Claudia Spits and Karen Sermon and will hopefully be a joint meeting with the SIG Stem Cells and Task Force Basic Science and Fertility Preservation.

Francesco Fiorentino is also preparing an **Update on PGS** to be

held towards the end of 2014, once results from some of the randomised controlled trials are published.

We hope that the two papers summarising our previous Campus meetings will be published soon - from our joint meeting with the SIG Ethics and Law, **Dynamics and ethics of comprehensive preimplantation genetic testing. A review of the challenges**, and from our joint ESHRE and the European Society of Human Genetics meeting, **Current issues in assisted reproduction and genetics in Europe; research, clinical practice and policy**.

We are now looking forward to the annual meeting in London, where will be hosting a pre-congress course on **Genes and epigenetic mechanisms of infertility and how to minimize the risks**. Our pre-congress course in 2014 will be an update of PGD/PGS.

Joyce Harper

Co-ordinator SIG Reproductive Genetics

Steering committee changes for the PGD Consortium

In September Edith Coonen accepted the vote of the steering committee to become Chair Elect of the PGD Consortium. However, on a not-so-happy note the committee had to say goodbye to Tugce Pehlivan and Leeanda Wilton. Tugce's job-change took her to an IVF centre which does not so far do PGD, while Leeanda, proposed as a nomination for Chair Elect, works in Australia and, as a non-European, did not meet the ESHRE criteria. All steering committee members wish to thank Tugce and Leeanda for their valuable contribution to the PGD Consortium over many years; we will miss them both very much.

The Accreditation working group, chaired by Katerina Vesela, did not go ahead with its joint workshop with Eurogentest in Istanbul in October because of the low number of registrations. However, the interest of PGD centres to

achieve accreditation continues. This is reflected in a recent announcement from a centre in Spain, a member of the PGD Consortium since 2005, that they achieved the ISO 15189 accreditation for PGD. Katerina has plans to organise an informal meeting of accredited PGD centres during the next ESHRE annual meeting in London to share experience.

External quality assurance

Related to the issue of quality assurance in PGD practice is external quality assessment (EQA). The PGD Consortium plays an active role here through the PGD

EQA Specialist Advisory Group, chaired by the steering committee member Sioban SenGupta, in collaboration with UK NEQAS and CEQA. With respect to molecular PGD EQA, four schemes have been run so far in collaboration with

PGD Consortium steering committee

The current steering committee of the PGD Consortium comprises Joanne Traeger-Synodinos (GR) Chair, Edith Coonen (NL) Chair Elect, Joyce Harper (GB) Past Chair, Céline Moutou (FR), Sioban SenGupta (GB), Katerina Vesela (CZ), Francesco Fiorentino (IT), Martine De Rycke (BE), Pam Renwick (GB), and Georgia Kokkali (GR).

Popular course at ASRM soon to be repeated

In early October we met in Athens for a workshop on **The best sperm for the best oocyte**, arranged with the SIG Andrology. The course was focused on gamete selection, fertilisation and embryo development, seen from both a sperm and oocyte point of view, as well as from an andrologist's and embryologist's view. The course was very successful, with high quality lectures and a lot of interaction from all parts of the audience. Our local host, Stamatis Papaharitou, provided us with excellent facilities and treatment, including a guided tour through Athens night (evening) life.

Later in October, the SIG Embryology hosted ESHRE's annual postgraduate course at the ASRM congress, this year in San Diego. The course concentrated on the interaction of the sperm and the egg. The course was fully booked (200 participants), and we received much interest and participation from the audience.

Renewal of the clinical embryologist certification

So far, 246 senior embryologists from the first year (2008) have renewed their certificate, 55% of those eligible. In the renewal process, official documents indicating eligibility for credits must be uploaded. The certified embryologists of 2009 (or from 2008 if they have not yet renewed) can

Steering committee

Kersti Lundin (SE), Co-ordinator
Maria José de los Santos (ES), Deputy
Carlos Plancha (PT), Basic science
Cristina Magli (IT), Past Co-ordinator

begin uploading their documents from this month (January 2013) until end of June 2013. Please note that renewal of certification is voluntary, provided as a service to our members. Please look at our web page for more information.

Coming courses

We will have a quick repeat of last year's ASRM course (as above) in Gothenburg, Sweden, in April, so please keep an eye on our website for further details.

For the annual meeting in London we have put together a pre-congress course on Cryopreservation - **What is hot and what is cold?**, which will cover most aspects on this topic, from gametes and embryos to ovarian and testicular tissue, including the possibility of contamination and molecular changes during cryopreservation.

The SIGE steering committee

The composition of the SIGE steering committee is changing. Both Junior Deputy Ana Sousa Lopes and Deputy Josephine Lemming have stepped down because of changes in their working and family lives. They will be replaced during the early Spring of 2013.

Kersti Lundin
Co-ordinator SIG Embryology

UK NEQAS and Dr Sandi Deans: three for cystic fibrosis and one for fragile X. The first two schemes (2008-2009 and 2009-2010) were run as pilots for members of the PGD Consortium, and in 2010-2011 a full scheme was offered. The results of these three schemes have resulted in a recent publication in the *European Journal of Human Genetics*.¹ Finally, a pilot EQA for array CGH is being organised jointly by NEQAS and CEQA.

The Misdiagnosis monitoring and audit working group, chaired by Jan Traeger-Synodinos, has been writing up the final details on the results of a collaborative ESHRE PGD Consortium study to evaluate PCR-based PGD following the re-analysis of untransferred embryos. The plans are to submit the paper very shortly.

The Database working group chaired by Céline Moutou is progressing with its major tasks, the first to perform statistical analysis of the cumulative data collected by the Consortium from 2001-2008 and the second to support the design and set-up of a new database to facilitate on-line real-time data collection. With respect to the cycles performed in 2009, the data are now being evaluated in

preparation for the next ESHRE PGD Consortium data collection (data XII).

Education

The recently started Education working group, chaired by Georgia Kokkali, intends to progress with plans to initiate interactive webinars for exchange of experience, case discussion and problem-solving between members of the Consortium, and eventually perhaps more widely. The Consortium has already run a pilot of the interactive webinar for steering committee members, which was a case presentation and very successful. Joyce Harper, Chair of the SIG, Jan Traeger-Synodinos (Chair of the PGD Consortium) and Georgia Kokkali recently had a meeting in Athens where they drafted a proposal for e-learning which was sent to ESHRE and the Chairman of the SIGS sub-committee.

1. Deans Z, Fiorentino F, Biricik A, et al, The experience of 3 years of external quality assessment of preimplantation genetic diagnosis for cystic fibrosis. *Eur J Hum Genet* 2012. doi: 10.1038/ejhg.2012.244.

SPECIAL INTEREST GROUPS

// REPRODUCTIVE SURGERY //

The case for training in reproductive surgery

Reproductive surgery is becoming a very complicated subspecialty of ObGyn practice. In the last 10 years we have seen tremendous improvements in infrastructure (settings and instrumentation) as well as the better ability of individuals and groups to help infertile women

become pregnant spontaneously or improve their chances with IVF. Appropriate surgery in an infertile woman with endometriosis gives her more than a 50% chance of spontaneous conception, while salpingectomy in a sactosalpinx will significantly improve the ART results - as well as preserve the ovarian microvascularisation.

There is enough experience and evidence-based data to show that reproductive surgery performed by well trained and experienced surgeons will significantly improve fertility results, relieve patients from pain, and improve their quality of life. In addition, surgery undertaken by well trained gynaecologists contributes to patient safety and secures the profession a strong reputation.

In the past five years different authorities have developed educational and training programmes in the fundamentals of endoscopic surgery (such as laparoscopic suturing), hand skills, ergonomics and surgical approach, and management. These programmes have proved of huge benefit to both novices and experts, and their acceptance and support are now a necessity to secure the safety of infertile patients, and improve their spontaneous and assisted reproductive performance. Indeed, the data demonstrate that educational and training programmes can objectively improve surgical approach and hand skills in reproductive surgery. The workshop organised by the our SIG in Grado in 2011, with the title [How can surgery increase the success rate in ART?](#), provided interesting data and raised interesting questions on reproductive surgery education.

From the mid-1980s the dominant role that surgery once had in the early days of ART has been continuously eroded by social, clinical, legal and logistic factors. An ever-increasing female patient age challenged practitioners to bypass surgery and begin their treatments immediately in order to speed up the prospect of pregnancy. And because the surgery was often complex - especially for endometriosis and/or adhesions - patients and practitioners were persuaded to skip the choice of surgery and go straight to IVF.

However, ART legislation can also affect the promotion of surgery before ART. In Italy from 2004 to 2009 the prohibition of embryo cryopreservation and the low number of fertilisable oocytes led to a resurgence of pelvic

Steering committee

Vasilios Tanos (CY), Co-ordinator
TC Li (GB), Deputy
Gregoris Grimbizis (GR), Deputy
Natasa Kenda Suster (SI), Junior Deputy
Marco Gergolet (IT), Past Co-ordinator

surgery in an attempt to increase the success rates of ART. Similarly, the role of logistic factors can be important - endoscopic surgery requires dedicated facilities, skilled personnel and technologically advanced equipment, which may not always be available or affordable.

According to a 2010 survey carried out by ESHRE's Task Force on the Management of Fertility Units, 32% of the centres who participated (212 from all over the world) were free-standing units which only performed ART treatments. In order to contain costs, these centres will not usually have their own surgical facilities, but will refer appropriate patients to other clinics.

Patient safety and the new procedurally-based technology

The loss of tactile input is the major reason why minimal access techniques are difficult to learn. A threshold of 25-30 cases is mandatory before surgeons reach proficiency. And of course, this proficiency increases as the complexity of the procedures grows; 90% of injuries are predicted to occur during a surgeon's first 30 cases.^{1,2} Surgeons who performed procedures without additional training are three-times more likely to have at least one complication compared with surgeons attended additional training.

A 2007 Dutch report (summarised by Rudi Campo in Grado) on the unacceptable extent of serious complications in common laparoscopic procedures in general surgery and gynaecology in the Netherlands found that training in laparoscopic surgery had been compromised: by challenges to the traditional 'apprentice-tutor' model, the necessity of high-volume surgical procedures, and an insufficient availability of skilled mentors; by difficulties in the objective assessment of clinical competence on different surgical levels; continuous pressure on the cost-efficiency of procedures and risk management; and an ethical objective to limit morbidity and error rate.

Today's focus in reproductive medicine is mainly on the laboratory, but it is increasingly clear that the lab cannot solve every problem. And there is still strong evidence that reproductive surgical skills and imaging technology are central to improving the success rates of every fertility clinic. So it is time to take up this challenge and redefine the content and domain of the reproductive surgeon. It is our belief, therefore, that the scope of a reproductive surgeon should be broadened to include the diagnostic and therapeutic imaging modalities used in reproductive medicine, and an active involvement in continuous surgical training. The reproductive surgeon is born within a fertility clinic environment and has good knowledge and

Safety first for this year's Campus collaborations

The SIG SQART is one of the most versatile and covers a wide range of subjects in ART. We are often asked to collaborate with other SIGs and Task Forces in organising courses and debates on controversial topics. Our recent pregress course in Istanbul staged in collaboration with the SIG Reproductive Genetics proved very interesting and well attended. Our latest collaboration, with the Tissue and Cells Directive Task Force, was a workshop in Dublin, hosted by the TF's co-ordinator Edgar Mocanu, on regulation of quality and safety in ART. This is a hot topic considering how complex our field now is. The course, which is reported in more detail on page 14, was very well attended and evaluated very positively. We think this calls for a sequel . . .

Steering committee

Petra De Sutter (BE), Co-ordinator
Willianne Nelen (NL), Deputy
Arianna D'Angelo (UK), Deputy
Jan Kremer (NL), Past Co-ordinator
Kelly Tilleman (BE), Junior Deputy

ultrasound on simulation equipment, which will give the course a very practical aspect. Prestigious speakers will give an update on the latest developments in ultrasound and ART.

● Our pregress course in London has been planned in collaboration

with the SIG Ethics & Law on **Responsible innovation in medically assisted reproduction**. Our aim this time is to present an overview of issues, challenges and responsibilities relevant to the safety and quality of innovations in ART. We anticipate much interaction between speakers and audience, leading to a constructive exchange of opinions.

We have also been engaging in several debates which will result in position statements in 2013. In collaboration with the SIG Ethics & Law we are currently discussing the concept of experimental treatment in ART. When does a certain technique become innovative and when established? We expect to finish a consensus text on this subject soon.

In collaboration with the Cochrane Menstrual Disorders and Subfertility group we are also working towards the release of a syllabus containing summaries of all the evidence available, to guide clinicians and consumers in making informed decisions. This project is ongoing and coordinated by Willianne Nelen from our SIG.

Finally, we welcome any further collaboration with colleagues from different SIGs and any new ideas; please contact us at dangelo@cardiff.ac.uk or petra.desutter@ugent.be.

*Petra De Sutter, Co-ordinator
Arianna D'Angelo, Deputy
SIG Safety and Quality in ART*

Events for 2013

● **Bringing evidence based innovations to the clinic**, 7-8th February, Leuven, Belgium, in collaboration with the Paramedical Group. The course aims to look in detail at emerging techniques and how they should be introduced in a responsible manner, with evidence and safety and quality at the forefront. The course should be attractive to anyone interested in new techniques and innovation, with a focus on the laboratory, the clinic and the patient, with presentations on the improvement of psychosocial care.

● **Ultrasound in reproductive medicine**, Maribor, Slovenia, 7-8th March. All aspects of ultrasound will be covered during this two-day intensive course open to anyone with a special interest in ultrasound at any level of experience. There will be opportunities to practise

experience in reproductive medicine. Thus, the fundamentals of a good reproductive surgeon comprise a multidisciplinary training in imaging modalities and modern and current surgery techniques.

The aim should be to:

- Improve the chance of a healthy delivery in infertile patients
- Prevent sub-fertility and infertility in young patients with benign diseases undergoing surgery
- Preserve and maintain fertility of women undergoing surgery

It is for these reasons that we in the SIG Reproductive Surgery, and based on the evidence of data, will continue to target high-value scientific programmes to improve the

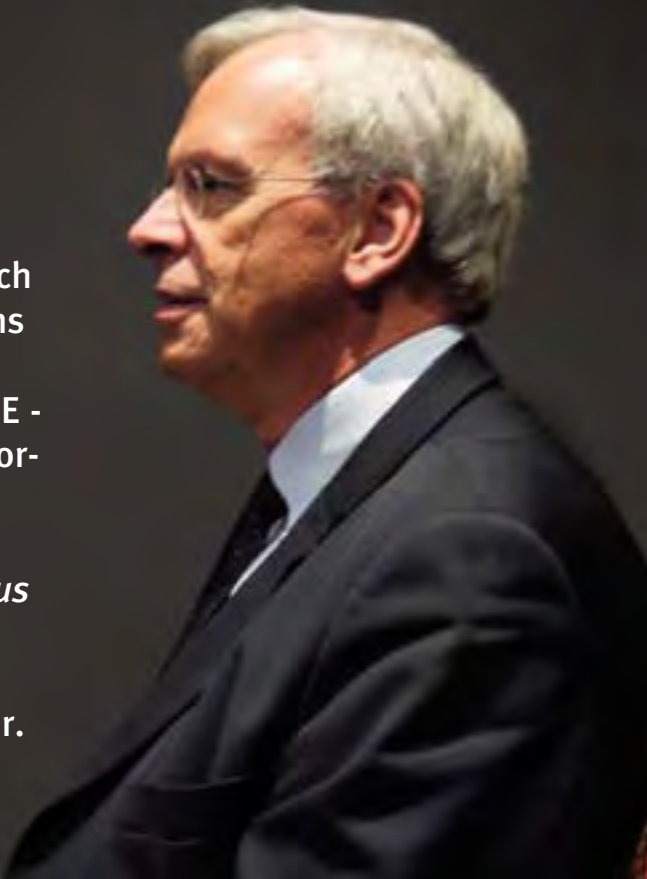
skills of the reproductive surgeon and the ability to diagnose and treat all the pathologies related to reproduction.

*Vasilios Tanos
Co-ordinator SIG Reproductive Surgery*

1. Gigot J, Etienne J, Aerts R, et al. The dramatic reality of biliary tract injury during laparoscopic cholecystectomy. An anonymous multicenter Belgian survey of 65 patients. *Surg Endosc* 1997; 11: 1171-1178.
2. Soot SJ, Eshraghi N, Farahmand M, et al. Transition from open to laparoscopic fundoplication: the learning curve. *Arch Surg* 1999; 134: 278-281.

This month the distinguished Dutch gynaecologist Hans Evers - a former Chairman of ESHRE - takes over as Editor-in-Chief of *Human Reproduction*.

He spoke to *Focus on Reproduction* about this next phase of his career.



Onwards and upwards for the 'world's best journal' in reproductive science and medicine

For: You're about to begin what could be a six-year term as Editor-in-Chief of *Human Reproduction*. How do you view the prospect?

I'm very excited to be taking over what is the world's best journal in our field. An impact factor of 4.475 is considerable, but there is still much to be done to raise it beyond 5. We are good at accepting good papers, but not so good at weeding out

the poor ones. My first objective is to improve the system such that we can better identify the poor papers. Even the young residents in our journals club in the hospital can find weaknesses, and that's frustrating to me.

And the biggest challenges?

There are two big challenges - electronic publishing and open access. I think that

by the end of my six-year term as editor we will mainly be publishing electronically, and it's difficult to predict what effect that will have, especially if it is enforced on us by the open access system. But certainly, the way we read journals is changing already. My young colleagues don't read printed journals any more. If they want to find something out, they Google it and a paper comes up - and it doesn't much matter where that paper comes from. But the older generation still seems to appreciate that manuscripts have been reviewed by scientists and clinicians with experience. And that's why there's a problem that people associate open access with unreviewed papers. So for me I think peer review will remain one of the mainstays of journal publishing and of our profession.

How will you manage your responsibilities as editor with those of your day job in Maastricht?

I am very fortunate. My university, with some financial support from ESHRE, has allowed me to spend four hours a day on *Human Reproduction*. So I'll have a half-time job on the journal and a half-time job to run my clinic. And that's a good division, I think. A journal which has more than 2000 manuscripts submitted each year means that every morning I can start with a few hours on those which have come in overnight, and then in the afternoons I can go back to gynaecology and surgery.

So your day-to-day working life be different?

Yes, it will be different. I will do fewer clinics, focus my research on smaller subjects and delegate more to my juniors. Anyway, at my age it's time to be a bit more contemplative.

You've had a distinguished career in gynaecology. How did your particular interest in IVF develop?

It's a salutary story. After I became a gynaecologist I trained in Belgium as a reproductive microsurgeon. But as soon as I'd become fully qualified in microsurgery IVF suddenly arrived and there just wasn't the demand for surgical work any more. Anyway, IVF was so much more efficient than spending eight hours repairing a tube.



'I JUST DECIDED THAT I WANTED TO MEET HIM. SO I WENT, AND THERE HE WAS AT THE ENTRANCE TO SHAKE OUR HANDS. BUT I WAS THERE BECAUSE OF HIS BOOK, AND THAT'S HOW I BECAME INVOLVED WITH ESHRE . . . THAT'S PURE INSPIRATION - FROM THE BOOK AND THE MAN.'

But IVF has changed a lot over that time?

Well, the whole business of infertility has changed. Originally, of course, all you could do was make the diagnosis - there was no good treatment whatsoever. There was clomiphene and some gonadotrophins, but they were scarce - so over the past 30 years treating infertility has developed from a purely diagnostic occupation into the very sophisticated treatments we have today. Now, we can offer people a chance, where 30 years ago there was no chance. Now, we have become a speciality which can diagnose *and* treat. That's the biggest change. We know how to treat, when to treat - and even when not to treat. The most difficult decision in medicine is when not to treat.

How did you get involved with ESHRE?

I had just finished reading the 1980 monograph of Bob Edwards on *Conception in the Human Female* and it had captivated me from beginning to end. And shortly after reading it I saw that the first ESHRE meeting was in Bonn, which was not too far from Maastricht. So I just decided that I wanted to meet him. So I

went, and there he was at the entrance to shake our hands. But I was there because of his book, and that's how I became involved with ESHRE. Now, I am a lifetime member of the Society. That's pure inspiration - from the book and the man.

Human Reproduction is, of course, an ESHRE journal. Does that affect your responsibilities as editor?

The Society and the journals are a unity - both have the same aim to stimulate research in reproduction in Europe by providing the profession with new ideas. ESHRE helps by making those developments available, through training, meetings, publications. So the journals and the Society work perfectly together.

You're still in Maastricht after many years. Were you never tempted to move elsewhere?

Yes, I've often been tempted - in fact, between 1986 and 88 I was in Riyadh in Saudi Arabia to start an IVF unit. But then I was offered a professorship in Maastricht and couldn't say no. So I am in Maastricht now, and it's from there that I will edit *Human Reproduction*.

The Proust questionnaire*

Your greatest virtue?

Choosing good collaborators and allowing them to develop.

Your favourite occupation?

Travelling.

If not yourself, who else would you be?

My grandson Jesper. He's two years old, sees an adventure round every corner and is always in a good mood. The politically correct answer would be Theodore Roosevelt. I admire him very much. He was in the depths of disaster but took up every challenge. I read his biography - 3000 pages and fascinating from one page to the next.



Your favourite film?

Manhattan, from Woody Allen.

Your favourite author?

Arto Paasilinna, a Finnish writer.

Your favourite food and drink?

Insalata Caprese and Ardbeg Uigeadail - but not together.



Your main fault?

My cluttered desk.

Your favourite piece of Music?

J.S. Bach's Goldberg Variations, preferably played by Glenn Gould (in his 1981 recording).

Your motto?

It's not the critic who counts, but the man in the arena - after Theodore Roosevelt.

* A personal questionnaire celebrated and originally made popular by the French writer Marcel Proust

Journal publishers explore potential of electronic and open-access publication

Apps for mobile access are now freely available for iPad and iPhone

The once cosy world of medical journals is in the midst of a publishing revolution. Thus, while the foundation stones of long-established titles, peer review and impact factors still underpin the medical journal business, publishers are now looking closely at the real and not-so-real opportunities of digital, mobile, personal and open-access services. And this applies to the ESHRE journals as to any others.

Only a few weeks ago both the ESHRE journals and *Fertility and Sterility* each introduced mobile apps, to give fingertip access to subscribers on the move. And those introductions came despite the likelihood that only a very small percentage of users will actually access the journals this way.

'Our strategy is mobile first, not app first,' says Phil Bishop, senior publisher for OUP's clinical medicine journals, which include the ESHRE titles. So only certain OUP journals - *Human Reproduction* included - will have their own app. 'The fertility sector does show high mobile usage,'

says Bishop, 'so it seems appropriate, but generally we can't see many readers consulting a full paper on a small screen.'

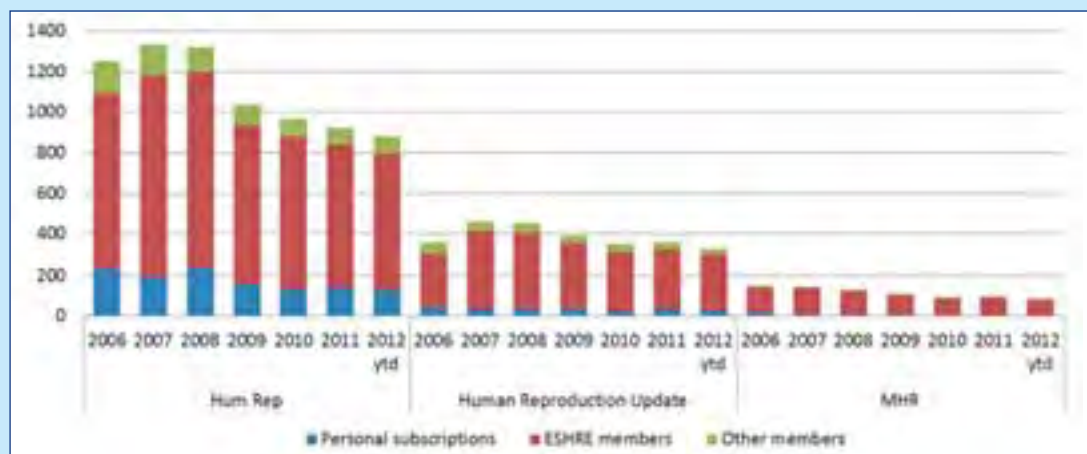
However, if the screen remains firmly fixed on the desk-top or laptop, how we arrive at that paper has changed remarkably in just a few years. Rarely do readers now browse a full printed journal, to dip into whatever takes their fancy. Instead, we are led via key words and citations to a paper of interest, which is then consulted as a downloaded PDF or HTML text. As a sign of the times, Google is now a more frequently used as a search service for OUP journals than PubMed or the journals' own websites.

So why keep the paper journal if usage is almost exclusively online? 'My personal opinion is that online-only will happen,' says Bishop, 'but I'd be hesitant to say when exactly. Right now we feel that subscribers appreciate the option of print.' And there are, of course, commercial reasons to retain that choice.

Advertising and reprints, for example, are revenue streams amenable to paper publication, even with the costs of print and mailing. Furthermore, despite the inexorable shift to online usage, there are still some personal and institutional subscribers who appreciate the feel of a paper copy.

'Certainly,' explains Bishop, 'we are exploring options for the ESHRE journals to move online at some point in the future. *MHR* has a low print circulation but a massive online readership, so that may well be the first title to change - but we don't yet want to force any customers away from print.'

Another development making its presence felt is open access, a demand arising from study sponsors and from publishing groups keen to provide an alternative medium for research. Funding bodies such as the NIH in the USA, and now the Medical Research Council and Wellcome Trust in the UK, are key proponents of free access to research they have funded. The ESHRE journals are already compliant with the NIH policy; all



Against a healthy institutional access circulation of between 4000 and 6000 per title, individual subscriptions to all ESHRE journals are declining slightly, although circulation among ESHRE members is holding up well.



papers are free to everybody online after a 12 month embargo period (the so-called 'green' access), and NIH-funded papers are deposited automatically into PubMedCentral. However, to comply with the MRC and Wellcome Trust's policies authors would have to publish under OUP's Oxford Open scheme and pay the relevant author processing charge. The Wellcome Trust has funds to pay these charges in what is a quite different business model (where the author and not the reader pays).

Clouding the water even further is a growing number of fully open-access journals, all of them without embargo restrictions before publication (known as 'gold' access). The revenue stream to their publishers is the fee paid by investigators for publication, which varies between \$500 and \$5000 per manuscript depending on the journal. In high volume publications such as *PLoS One* this is a considerable source of income.

Moreover, in open access journals the value assessment of the papers is shifted to the reader. 'The publisher has responsibility for editing and processing the manuscript,' says Bishop, 'but it's the reader – and not just the editor - who decides whether

Access to journals 2012

Human Reproduction

Total visits	2,965,292
via Google	1,589,559
via PubMed	178,365
via oxfordjournals	9,816
via eshre.eu	5,731

Human Reproduction Update

Total visits	777,151
via Google	361,815
via PubMed	59,262
via oxfordjournals	2,926

MHR

Total visits	384,287
via Google	147,083
via PubMed	46,010

Study sheds dark light on journal retractions

Two-thirds of retractions from academic journals are the result of fraud, suspected fraud or plagiarism, according to a new study.¹ The extent of the misconduct is much greater than thought, and has grown 10-fold since 1975.

'The disproportionately high payoffs to scientists for publication in prestigious venues can be an incentive to perform work with excessive haste or to engage in unethical practices,' the investigators wrote. The study, which reviewed more than 2000 papers listed as retracted since 1977 in PubMed, found that only 21% were attributable to error.

A *Human Reproduction* editorial in 2011 reported that retraction is an uncommon occurrence, with only three known cases in the entire history of the journal.² However, editor-in-chief André Van Steirteghem and managing editor Andy Williams did note that plagiarism (including 'ideas and concepts') is becoming increasingly common. They added that all submissions to OUP journals are now screened by 'anti-plagiarism' detection software, which already had identified (and still identifies) 'a number of manuscripts that contained sufficient plagiarism to result in their rejection'.

Recent months have seen several high-profile misconduct cases exposed (including influential Dutch cardiologist Don Poldermans and Japanese stem cell researcher Hisashi Moriguchi), and a less prominent retraction from *MHR* (doi: 10.1093/molehr/gas045) in which a university investigation detected the use of 'manipulated or falsified data' in a 2010 paper.

1. Fang FC, Steen RG, Casadevall A. Misconduct accounts for the majority of retracted scientific publications. *PNAS* 2012; doi:10.1073/pnas.1212247109
2. Van Steirteghem A, Williams AC. Plagiarism, retraction and the future. *Hum Reprod* 2011; 26: 1940.

the paper is worthwhile or not.' Indeed, another of the latest open access publishers, F1000Research, openly advertises that it will support the publication of research 'hard to publish in traditional journals' – such as negative findings, replication or refutation articles and 'small findings'. Publication would be immediate 'following a rapid internal review'.

OUP already has ten fully open access journals, and it is, adds Bishop, 'a business model we are keeping an eye on for possible impact on the ESHRE journals'. Are authors and readers in reproductive medicine keen on the *PLoS One* style, or do they continue to prefer the high quality, editorial screening currently in place in the ESHRE journals?

So far, Bishop adds that open-access uptake in the three ESHRE journals is 'generally low', with 13 articles in *Human Reproduction*, two in *Update* and three in *MHR* in 2012. Indeed, all OUP journals have seen an

overall decline in open-access papers in all subject areas since 2007.

But whatever the future, the ESHRE journals continue to be an important benefit of membership, with massively reduced subscription fees available.

Like the annual meeting the journals return a healthy profit to the Society, which helps support other ESHRE activities. So, says Bishop, however digital and open access publishing in the next few years evolves, ESHRE, the editorial teams and OUP will ensure that the service provided to authors and readers continues in the most appropriate manner – and most importantly, one that is fair to all.

OUP too receives a small share of the journals' profit, and, as a Department of the University of Oxford, this share is ultimately returned to the academic community in the form of grants and funding.

Simon Brown
Focus on Reproduction



Happy families

Assisted reproduction has created family permutations which were inconceivable 30 years ago. Professor Susan Golombok, Director of the Centre for Family Research in Cambridge, UK, reviews the evidence and asks what effects these new family relationships have had on parenting and child development.

In 2012 the number of children born as a result of assisted reproduction reached a landmark total of 5 million. In the early days, there was much concern about the potentially negative impact of ART on the well-being of children and their families. This article looks back at more than two decades of research on ART families and asks whether conceiving children through such high-tech procedures as IVF or ICSI, or through third-party involvement such as oocyte, sperm and embryo donation or surrogacy, have good, bad or no effects on parenting and child development.

In vitro fertilisation

Parenting in IVF families has been studied at different stages of child development from infancy to adolescence. Mothers of IVF infants in an Australian study were found to show greater concern about their baby and lower confidence as parents than a comparison group of natural conception mothers.¹ However, their concerns did not interfere with the quality of the mother-child relationship; for example, there was just as much sensitivity towards their infants as found in the natural conception mothers. In addition, few differences were identified between IVF and natural conception fathers.

Later, as children enter the pre-school and early school years, the anxieties of IVF mothers seem to diminish. Indeed, the European Study of Assisted Reproduction Families conducted in the UK, Netherlands, Spain and Italy found IVF mothers showing greater warmth towards their child. They were more emotionally involved, interacted more and reported less stress over parenting than natural conception mothers.² IVF fathers were described by mothers as interacting with their child more than natural conception fathers, and the fathers themselves reported less parenting stress.

By adolescence this more positive parenting was no longer apparent, although the IVF mothers and fathers maintained a good relationship with their adolescent children, characterised by affection and appropriate control.³

With respect to children, the Australian study cited above did find some evidence of more behavioural difficulties in IVF than in naturally conceived infants, although a Swedish investigation found IVF infants to be more manageable. Beyond infancy, research findings are more consistent, and children born after IVF seem to show no higher levels of emotional or behavioural problems than their naturally conceived counterparts in early childhood or adolescence.^{2,3} Similarly, when compared with general population norms, there are no indications of greater psychological problems in children conceived by IVF.

ICSI

Parenting in ICSI families has been found to be just as positive as in IVF families. A large-scale study of ICSI, IVF and natural conception families with a 5-year-old child in Belgium, Denmark, Greece, Sweden and the UK found few differences between family types, with the ICSI mothers reporting higher levels of commitment to parenting than the mothers of naturally conceived children.⁴ Similar findings have been reported from the Netherlands.

In terms of child adjustment, high levels of psychological well-being have been found among ICSI children, with no evidence of greater emotional or behavioural problems than found in IVF or naturally conceived children. However, because of concerns about the effects of ICSI on physical or brain development, attention has focused more on the cognitive functioning of ICSI children. For example, the Bayley Scales of Infant Development were administered to ICSI children in Belgium, with no evidence found of developmental delay.⁵ Similar findings were reported from the UK using a comparable assessment instrument.

In contrast, however, significantly lower scores were found among ICSI children in an Australian study, particularly among boys.⁶ Seventeen per cent of ICSI children showed mildly or significantly delayed development compared with 2% of the IVF and 1% of the naturally conceived children. However, when these same Australian children were followed up at age 5 (and with an increased sample size), no differences were identified between the ICSI children and comparison groups of IVF and natural conception children.⁷ In line with this finding, no evidence of greater cognitive impairment in ICSI than in IVF and natural conceived children has been found in other studies performed in Europe and the USA.

Families from reproductive donation

While IVF and ICSI remain the traditional methods of assisted conception, there is a growing number of children being born through gamete and embryo donation and surrogacy. Successful sperm and oocyte donation both result in the absence of a genetic link between the child and its mother or father, while in embryo donation the child is genetically unrelated to both parents, a situation similar to adoption (apart from the experience of pregnancy and birth). In gestational surrogacy the child lacks a gestational link to the mother, while in genetic surrogacy the child lacks both a genetic and gestational link to the mother.

Through the application of these techniques it is now possible for a child to have five 'parents' – an egg donor, a sperm donor, a surrogate mother who hosts the pregnancy and the two social parents whom the child knows as mum

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and dad, or mum and mum in the case of lesbian partners, or dad and dad when the parents are gay fathers.

There has been widespread concern that the creation of families through donated sperm, oocytes or embryos, or through the involvement of a surrogate, may have a harmful effect on family relationships and the children's psychological adjustment, resulting either from secrecy about a child's biological origins, or from the absence of a biological connection between one or both parents and the child. Indeed, assisted reproduction using donor gametes remains illegal in several countries, even in Europe, and surrogacy is illegal in many.

Concerns about secrecy in donor conception families arose from research on adoption showing that adopted children not given information about their birth parents were at an increased risk of emotional, behavioural and identity problems. The family therapy literature also points to the potentially negative psychological effects of keeping a child's origins secret.

The view that the absence of a genetic and/or gestational connection between parents and children may be detrimental to positive family functioning similarly derives from the study of adoptive families (or stepfamilies, in which one parent lacks a biological link). However, that research also suggests that any child adjustment difficulties are more related to factors associated with adoption (such as maltreatment before the adoption took place) rather

than to the absence of a biological link to the parents.

Such views are complicated by the fact that ART has made possible new family forms, such as lesbian mother families with children conceived by donor insemination, gay father families with children born through surrogacy and egg donation, and families headed by a single mother by choice.

Children born to gay men through surrogacy may have two 'mothers' and two fathers - a gestational mother, a genetic mother, a genetic father and a social father, but no mother in the family home. For children born by donor insemination to lesbian couples or single women, their father is a sperm donor whom they may never meet and whose identity they may never know.

Although there has been much controversy about the use of reproductive donation for the creation of these non-traditional families, the Ethics Committee of the ASRM has concluded that requests for assisted reproduction should be treated without regard to sexual

orientation or marital status. Recent legislative changes relating to the practice of ART have similarly enabled lesbian women, gay men, and single heterosexual women to become parents. However, while recent legal changes in the UK have strengthened the parental rights of lesbian and gay couples (and single women), their fertility treatment in France remains illegal, and, despite legal challenges, any third party gamete donation is still outlawed in Germany and Austria. Even Sweden, applauded for its progressive approach to single embryo transfer and multiple pregnancies, has only recently assessed the legitimacy of surrogacy and the treatment of single women.

Disclosure of reproductive donation

Our early research found that the majority of parents who gave birth to donor-conceived children did not tell them about their genetic origins. Indeed, not one set of the 111 donor insemination parents who participated in the European Study of Assisted Reproduction Families had done so by early school age, and less than 10% by early adolescence.^{2,3} A similar pattern was found among families with a child born as a result of egg or embryo donation.

When questioned about the reasons for their secrecy, parents of donor-conceived children said they were apprehensive about jeopardising the positive relationship

with their child. Furthermore, they did not know when or how to inform the child, and were concerned about being unable to identify the donor.

More recently, and following legal requirements in some countries to remove anonymity from donors, there has been a rise in the number of parents who intend to tell their children about their donor origins. However, despite such intentions, many parents do not disclose this information. In our UK study of children born at the Millennium, 46% of parents of infants conceived by donor insemination and 56% of parents of infants conceived by egg donation planned to inform their child, but, by age 7, only 28% and 41% of parents respectively had actually done so.⁸ Some of the ‘disclosing’ parents had discussed the use of fertility treatment, but not donor eggs or sperm (although the children in this study were born before the removal of donor anonymity in the UK in 2005).

However, contrary to their parents’ concerns, children who are told about their donor conception in their preschool years have been found to respond neutrally or with curiosity, rather than with distress.⁹ Indeed, those who find out about their donor conception in adolescence or adulthood are more likely to report feeling distressed than are those told in childhood.

With the removal of donor anonymity in some countries - and the rights of the child to know the identity of the donor on reaching adulthood - there have been questions about the child’s future relationship with the donor. Studies so far suggest that some young people are curious to know what their donor is like, and plan to make contact. However, very few report wanting a father-child relationship.

Parenting and child adjustment

Few studies have investigated parenting or children’s psychological adjustment in families formed through reproductive donation. The European Study of Assisted Reproduction Families found no differences in emotional or behavioral problems between children conceived by sperm or egg donation and comparison groups of IVF, naturally conceived and early-adopted children.^{2,3} Similarly, no differences in the psychological adjustment of 5-9-year-old children were found in a study comparing sperm donor-conceived families with those created by ART.¹⁰

A follow-up of our Millennium study of families where parents had told children about their donor conception found that the children were as well adjusted as their counterparts from natural conception families.¹¹ It was concluded that the positive outcomes for the donor families reflected the parents’ high levels of commitment to parenting given the difficulties they had had in their quest for a child.

Although, the donor conception mothers who had kept their child’s origins secret showed higher levels of emotional distress than those who had been open about their child’s origins, the differences identified were not indicative of psychological problems but instead reflected variation within the normal range.

Lesbian mothers, gay fathers and single mothers by choice

Increased access to fertility treatment has seen a growing number of lesbian women becoming parents through ART, particularly donor insemination. The first studies of such families began to appear in the mid-1990s, and have since

Children's socio-emotional functioning according to family types³

	IVF		DI		Adoptive		Naturally conceived	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Child's interview								
Interest/effort in schoolwork	2.69	0.86	2.85	0.86	2.68	0.79	2.82	0.72
Confidence in school performance	1.94	0.70	1.94	0.75	1.78	0.65	1.90	0.63
Time spent with peers	3.98	2.11	3.04	2.10	4.23	1.97	3.22	1.96
Confidence with peers	2.11	0.63	2.13	0.54	2.15	0.65	2.09	0.53
Verbal aggression towards peers	0.30	0.65	0.48	0.69	0.41	0.73	0.51	0.83
Physical aggression towards peers	0.11	0.32	0.17	0.41	0.11	0.41	0.27	0.53
SDQ measures								
Total problems score - rated by mother	7.68	5.46	7.66	4.89	7.03	4.43	7.77	5.22
Total problems score - rated by teacher	6.26	6.31	6.70	6.27	5.98	4.67	6.23	3.84
Prosocial behaviour - rated by mother	7.77	1.87	7.66	2.17	7.33	2.03	7.60	1.96
Prosocial behaviour - rated by teacher	7.37	2.12	7.04	2.33	7.14	1.89	6.94	2.06

DI = donor insemination; AR = assisted reproduction; NC = naturally conceived; A = adoptive; NS = not significant; SDQ = Strengths and Difficulties Questionnaire (a measure of child adjustment problems)

Rating results from interviews for the European Study of Assisted Reproduction Families follow-up found no differences between children from the different family types in relation to interest/effort in schoolwork or confidence in school performance. The time spent with peers did not differ between assisted reproduction children and natural conception children. There were no differences between family types in children’s total problems scores or prosocial behaviour scores as rated by mothers or teachers.

then shown consistently that the children born to lesbian mothers are no different from children in heterosexual families with respect to gender development, peer relationships, or psychological well-being in childhood or adolescence.

In recent years there has been an increase in the number of gay men who are raising children. Although this has arisen through several routes, including post-divorce custody arrangements, adoption and co-parenting with lesbian women, greater accessibility to ART has resulted in a small but growing number of gay men having children through surrogacy, usually in combination with egg donation from another woman. No studies of children born to gay fathers through surrogacy have yet been published. However, a US study of 2010 found that young children adopted early in life by gay fathers were as well adjusted as those adopted by lesbian or heterosexual parents. Similarly, our UK study found adoptive gay father families to be functioning as well as comparison groups of adoptive lesbian and heterosexual families.

Concern about children born to single heterosexual mothers through donor insemination is based on research showing negative psychological outcomes for children raised by single mothers following divorce. However, in contrast to divorced mothers, single mothers by choice are generally financially secure with good social support, and their children have not been exposed to parental conflict or family disruption.¹²

Nevertheless, the combination of two controversial pathways to parenthood – donor insemination and single motherhood – together with the absence of a known father may place these children at increased psychological risk. Research is currently ongoing at the Centre for Family Research on parenting or child adjustment in these families.

Conclusions

The growing body of research on families formed through ART with or without the use of donor insemination, egg donation, embryo donation or surrogacy shows that concerns about the potentially adverse outcomes for parenting and child development are largely unfounded. Where difficulties have been identified, they appear to be related to factors associated with the method of conception, such the discovery in adolescence or beyond of being donor conceived, rather than the method of conception in itself. Although less is currently known about non-traditional than traditional families formed through reproductive donation, there is no evidence to indicate that these new family forms may be at risk for parenting or child adjustment problems.

Overall, the findings suggest that the processes that operate within families, such as positive parenting and

open communication, are more important for child adjustment than structural variables, such as the presence of a genetic or gestational connection between the parents and the child.

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