



British
Fertility
Society

BFS STUDY WEEK

19-22 June 2017

Effective Fertility Services e-PROGRAMME

In Association with



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Millennium Gloucester Hotel, Kensington, London

www.bfsstudyweek.org.uk

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FOREWORD

On behalf of the BFS I would like to welcome you all to *Study Week 2017*, which will be the largest one yet. Those of you who have been before will notice many changes. To accommodate our rapid growth, we have moved venue to the very pleasant Millennium Gloucester Hotel. To ensure that you have the latest up to date information and to make the event more 'green' and efficient we have gone 'paperless'.

We are delighted to have two new additional *Study Days* this year (*Fertility Nursing* and *PGD/PGS*) and there have been changes to some of the existing *Study Days* too, to ensure that you are getting the very best experience. I would like to thank the Speakers for taking time out of their busy schedules to come and teach at the event; as well as the sponsors who generously support our educational program.

I would particularly like to thank the delegates for coming, because you really make the event the success that it is. We hope that you all enjoy it and leave London with knowledge that will aid your personal development and the care of your patients. Please ask the speakers questions, we are here for you.

If you aren't already a BFS member, please consider joining and also, consider enrolling for the highly regarded *BFS Training Modules* that are linked to many of the *Study Days*. All the relevant details are on our website www.fertility.org.uk. Feel free to share your opinions on social media @BritFertSoc and @UKEmbryologists and do please complete the feedback form which will be sent to you after the event online, we want to know what you think.

Now, get ready, it's time to be educated!

All the very best wishes,



Kevin McEleny
Chair of Education and Training
British Fertility Society

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EFFECTIVE FERTILITY SERVICES PROGRAMME

CROMWELL ROOM 4

08.00 Registration, welcome refreshments, exhibition

09.00 Chairs' opening welcome *Simon Wood, Ellen Armstrong*

09.10 The HFEA perspective: ensuring quality & preparing for inspection *Sharon Fensome Rimmer*

09.55 What is expected of HFEA person responsible *Yacoub Khalaf*

10.30 Refreshments, exhibition and networking

11.00 Clinical and laboratory, the centrality of consent *Sue Avery & Sharon Fensome Rimmer*

11.45 Understanding your budget & tips for financial viability *Sue Avery*

12.30 Lunch, exhibition and networking

13.30 How best to give patients bad news *Kate Brian*

14.15 How to cope with giving bad news and how to support each other during times of stress *Jenny Dunlop*

15.00 Refreshments, exhibition and networking

15.30 Delivering Bad News Professionally and Sensitively (interactive session) *Jenny Dunlop*

16.15 Embryology Horizon scanning - Opportunities and challenges *Rachel Cutting*

17.00 Close of day and Networking

EFFECTIVE FERTILITY SERVICES PROGRAMME

CROMWELL ROOM 4

08.00 Welcome refreshments, exhibition

08.55 Chairs' opening welcome *Simon Wood, Ellen Armstrong*

09.00 Business Planning for service development *Jonathan Koslover*

09.45 Effective strategies for running a successful fertility service *Marco Gaudoin*

10.15 Change Management: preparing people and process for change *Valentine Akande*

10.45 Refreshments, exhibition and networking

11.15 Introducing a new service *Raj Mathur*

12.00 Fertility horizon scanning *Yacoub Khalaf*

12.45 Lunch, exhibition and networking (45 minutes for lunch)

13.30 Strategic tools for management *Jonathan Koslover*

14.00 Legal and reputational risk in assisted conception *Antonia Foster*

14.30 Public relations and issues management *Claudia Rubin*

15.00 Refreshments, exhibition and networking

BFS & ACE PARALLEL SESSIONS

CROMWELL ROOM 4

BFS parallel session

15.30 The UK fertility market - understanding NHS commissioning and the private market *Charles Kingsland*

16:00 How does the Quality Manager establish an effective quality management system? *Nilendran Prathalingam*

16:30 Establishing a robust performance enhancing appraisals framework *Raj Mathur*

CROMWELL ROOM 1

ACE parallel session

15.30 Selecting the best statistical test for your dataset (interactive session)
Interpreting data and presentation of results

Christine Leary

17.00 Close of BFS & ACE Parallel sessions

EFFECTIVE FERTILITY SERVICES ABSTRACTS AND BIOGRAPHIES

The HFEA perspective: ensuring quality & preparing for inspection

Sharon Fensome Rimmer

Key learning Points:

Participants should be confident in preparing for HFEA inspections and understand the HFEA's expectations in terms of the delivery of audit of practice and monitoring of performance.

The presentation aims to provide background to the focus and purpose of HFEA inspections and how centres can prepare for inspection. Providing a good quality service to patients is obviously paramount and the presentation also touches on how centres should be auditing their practice to deliver improvements and how HFEA data can support these efforts. Participants are expected to have knowledge and/or experience of HFEA inspections; the HFEA Act and related legislation and the HFEA Code of Practice. The HFEA must carry out effective licensing and regulation consistent with the requirements of the legislation.

We must have the right impact in the right way, adding value to the sector while taking account of the experiences of our stakeholders and of patient and public concerns and perceptions. The HFEA uses a combination of focused unannounced or short notice interim inspections and scheduled renewal inspections in our regulatory model. For the sector, unannounced or short notice inspections mean less time preparing for inspection and more time spent ensuring on-going inspection readiness. They focus on observation of laboratory activities (mainly witnessing), getting feedback from patients and auditing patient records.

The findings of interim inspections are supplemented in the report with information gathered in the course of on-going monitoring. Renewal inspections continue to be fully scheduled, sometimes over two days for bigger centres, and require centres to be able to demonstrate compliance with all relevant requirements. Centres should prepare for renewal inspections by considering what evidence of compliance can be made available to the inspection team and which member or members of the team are best able to provide the evidence. Completing a self-assessment questionnaire should help identify areas of practice that require improvement in advance of the inspection. The establishment of quality indicators and development of effective audit programmes are essential to ensuring quality. Standard license conditions require licensed centres to do both. If centres are fully implementing the requirements of the 8th Code of Practice they should already be ensuring quality.

To support centres in their efforts to ensure quality, outputs from the HFEA's risk based assessment tool (RBAT) are available to centres through the HFEA clinic portal. When monitoring indicates a dip in performance centres receive an alert from the HFEA and it is expected that when such an alert is received, centres will review practices to identify where there are opportunities for improvement and implement changes aimed at delivering improvements. Some time will be spent reviewing some common themes as regards to what centres do well and not so well.

Sharon Fensome Rimmer is a registered scientist and a Chartered Quality Professional and has worked within science & quality since 1988. Sharon started her career within quality control, trained as a Scientist within the NHS gained a Masters degree in Biomedical Science, becoming a fellow of the institute of Biomedical Science and achieving Chartered Scientist Status. She has undertaken further training in the field of Quality and has also achieved the status of Fellow of the Chartered Quality Institute. As both a Health and Care Professions Council registered Scientist and Chartered Quality Professional Sharon has a unique insight into the Health Care Sector having worked in laboratories & governance.

Sharon is the Chief Inspector of the Human Fertilisation and Embryology Authority.

What is expected of HFEA person responsible

Yacoub Khalaf

Key Learning Points:

1. To understand the legal role of the HFEA Person Responsible
2. To appreciate the expectations of the HFEA Person Responsible as well as the sanctions that could apply to the clinic or the Person Responsible if it was thought there was failure in discharging the duties of the role
3. To understand who qualifies for the role of Person Responsible and the training required

The HFEA Person Responsible is a specific legal role defined by the Human Fertility Embryology Act 1990. The act expects each clinic to have a named person responsible who is the individual regarded as having supervisory responsibility for the activities licensed under the provisions of the act. The HFEA Person Responsible ensures that the clinic complies with the requirements of the law and HFEA Code of Practice.

Further reading The HFEA code of practice (8th edition) which can be found on the HFEA website.

Yacoub Khalaf is a Consultant/Senior Lecturer and subspecialist in Reproductive Medicine & Surgery, Guy's & St. Thomas' Hospital and King's College, London

- Head of Fertility Services and Director of Assisted Conception Unit & Centre for Pre-implantation Genetic Diagnosis
- Member of the Human Fertilisation & Embryology Authority (HFEA) Board.
- Executive Officer of the British Fertility Society
- Chair of the Scientific and Clinical Advances Committee of the HFEA
- Chair of the RCOG National Clinical Study group in Reproductive Medicine & Surgery
- Member of the RCOG Research Committee
- Expert advisor to the National Institute for Health Care & Clinical Excellence (NICE)
- Ex-Associate Editor of the RBM online Journal
- Grant Reviewer for the National Institute for Health Research in the UK
- Director of the International Exchange Programme in ART and Fertility Imaging courses at Guy's and St Thomas' Hospital Foundation Trust
- Principal Investigators/clinical adviser of several NIHR funded research grants
- Supervisor and examiner of Masters, MD and PhD candidates for various UK universities
- Published widely on different aspects of Assisted Conception, Reproductive Medicine & Surgery
- Lectured on ART at most national and international conferences

Clinical and laboratory, the centrality of consent

Sue Avery & Sharon Fensome Rimmer

Key learning Point:

Participants should be confident in understanding the law as regards consent and the steps they need to be able to take to be able to demonstrate their compliance with the law.

On 1 April 2015, the HFEA published an update to the Code of Practice, consent forms, General Directions and licence conditions all relating primarily to the giving of consent by patients. The presentation outlines those changes and the impact this will have on staff working in licensed clinics. Informed consent is one of the most important principles in healthcare and a fundamental feature of the Human Fertilisation and Embryology Act 1990 (as amended). Clinics are under a statutory responsibility to ensure that properly informed consent is given by their patients. The session explores new requirements and guidance being introduced to embed clinics' adherence to legal requirements.

Sue Avery is the Director of The Fertility Centre at Birmingham Women's Hospital. She has been working in the field of infertility for since 1981, and wrote her PhD thesis under the supervision of Professor Robert Edwards. She has a postgraduate diploma in Law, and was the first Clinical Embryologist to be appointed to the HFEA. Sue was the Chair of the Association of Clinical Embryologists from 2003 to 2005 and the treasurer of the British Fertility Society from 2011 to 2015, and was one of the first embryologists to be granted fellowship of the Royal College of Pathologists.

Sharon Fensome-Rimmer Biography see page 5

Understanding your budget & tips for financial viability

Sue Avery

Key Learning Points:

1. Interpretation of budget sheets
2. Understanding the sources of income as well as expenditure
3. The importance of having enough information to defend your financial position

Understanding your budget & tips for financial viability

Anyone with responsibility for managing a Fertility Service, regardless of background or training, needs to have a detailed understanding of their budget and accounts. With increasing pressure to save money it is important to look ahead and be able to defend your position if cuts are threatened that may damage the viability of your service and impact negatively on patient safety, quality of service, and potential income. NHS services may find it difficult to identify the sources and quantity of income, as income from block contracts may not be aligned with other income streams. Knowing how much income you generate, as well as your expenditure is vital.

Biography see above

How best to give patients bad news

Kate Brian

This session will focus on the patient experience of hearing bad news, and what can make this particularly challenging to handle. It will include some real life experiences and will discuss what can go wrong and how clinics can improve the way they deal with breaking bad news to patients.

Kate Brian is London Representative of Fertility Network UK and Women's Voices Lead at the RCOG. She is a member of the HFEA and edits the Journal of Fertility Counselling. She was a member of the NICE fertility guideline development group. Kate began her career as a television journalist working at the BBC, ITN and Channel Four News, where she specialised in health and science. Kate has written four books about fertility for a lay audience including The Complete Guide to IVF and Precious Babies - Pregnancy, Birth and Parenting after Infertility. She presented the BBC Radio 4 documentaries Banking on Birmingham and The New Viking Invasion.

How to cope with giving bad news and how to support each other during times of stress

And

Delivering Bad News Professionally and Sensitive (interactive session)

Jenny Dunlop

Key Learning Points:

1. To become more aware of the effects of stress on both patients and staff.
2. How to develop further beneficial coping strategies to help your self and staff in your team.
3. To look and learn from guidelines to help in breaking bad news and interactively to put into practice ways of doing this difficult work with relevant case studies.

No member of staff wishes to be the messenger of upsetting information but it is part of the professional work for most staff within a fertility clinic. It is never easy, can be extremely demanding, stressful and have a lasting effect on both patients and staff. We can all learn to improve our ability to tell 'bad news' which can be beneficial to both patients and staff. Owning the effect that this can have on our own emotions honestly is a start to helping how we care for both patients and ourselves. If patients can have confidence in the openness and honesty of staff it can help them become more confident in their own ability to cope. The first presentation will include looking at how to cope with stress for the individual and how to support the team. The second presentation will look at guidelines for breaking bad news and will include interactive work with anonymised case material.

Jenny Dunlop is an experienced Counselling Practitioner. She has specialized knowledge of working with people who have fertility problems. She has worked in units in both the private and NHS sector. She was the counsellor representative on the 2004 NICE Fertility Guideline Group. She has always been interested in staff development and started training courses for her professional association (BICA) as well as running courses, such as 'Breaking Bad News' for multi-disciplinary teams in Fertility Clinics. She has an extensive Supervision Practice with Counsellors coming from different Agencies. She was previously an Inspector and Lay Adviser for the HFEA.

Embryology Horizon scanning - Opportunities and challenges

Rachel Cutting

Key Learning Points:

1. Review evidence of latest techniques available to the IVF laboratory
2. Understand why evidence and validation of new technology is important
3. Highlight promising technology for the future

Assisted reproductive technology advances rapidly and we often attend meetings and listen to presentations describing promising studies with new methods and practices. However, new technology must be validated and it is good practice to only introduce new procedures clinically with a good evidence base, for example after well designed randomised controlled trials. In reality though this is difficult to achieve as funding for such studies is limited and the bureaucracy to wade through is lengthy. There are many innovations which may be seen as opportunities to improve success rates. This talk will review new technology on the horizon and whether there is evidence for its inclusion into clinical practice.

Rachel Cutting graduated from the University of Nottingham in 1995 and completed the ACE post graduate diploma in 1998. In 2001 she gained the position of Principal Embryologist at Jessop Fertility and holds the position of Person Responsible. Rachel was chair of ACE from 2011-2014 and is an assessor for the ACS and NSHCS. She is involved in writing the national curriculum for training embryologists and has written national guidelines for oocyte freezing and elective single embryos transfer. She was awarded an MBE in 2015 for services to infertility.

EFFECTIVE FERTILITY SERVICES ABSTRACTS AND BIOGRAPHIES

Business Planning for service development

Jonathan Koslover

Key Learning Points: TO BE ADDED

Effective strategies for running a successful fertility service

Marco Gaudoin

Key Learning Points:

1. The patient must feel that you have done your best for her.
 2. Team-working and team development is essential for a successful service
 3. Good communication is paramount
- Minimise the risk of OHSS and maximise fresh embryo transfer rates
 - Optimise the rates of elective single embryo transfer
 - 7-day working allows blastocyst culture and natural cycle-frozen embryo transfer

 - Patient selection and number of embryos to transfer
 - Customer satisfaction and dealing with complaints
 - Monitoring and analysis of incidents and complaints? recurrent themes
 - Experience must be positive, especially when not pregnant

 - Team-working and team development

 - Staff must want to come and work with you
 - Invest in staff development and education
 - Allow staff "ownership" of projects
 - Constant review (KPIs)
 - Efficient working practices
 - Good communication is paramount

Marco Gaudoin, MBChB, MD, FRCOG - Medical Director, GCRM. Marco graduated from Edinburgh in 1987. Undertook General Practice training prior to O&G training. His MD thesis was on non-invasive prenatal diagnosis. He has been involved in the fields of reproductive medicine and infertility since 1995, setting up an assisted reproduction programme in South Glasgow in 1999. His first consultant post was in England but he returned to South Glasgow in 2002 and he has worked fulltime at GCRM since March 2010. He has published widely in all areas of reproductive medicine and continues to pursue these research interests.

Change Management: preparing people and process for change

Valentine Akande

Valentine Akande MBBS PhD MRCOG, is the Lead Clinician and Person Responsible at the Bristol Centre for Reproductive Medicine (BCRM), Southmead Hospital. He was a clinical research fellow under the late Professor Michael Hull and later clinical lecturer in Reproductive Medicine at the University of Bristol & St Michael's Hospital, Bristol. His research interests have led to numerous publications. He is an elected member of the BFS executive committee and chairs the meetings and conferences Sub-Committee. He previously served on the subspecialty training committee of the RCOG and is also a medical performance assessor for the General Medical Council (GMC) and the RCOG.

Introducing a new service

Raj Mathur

Raj Mathur trained under Professor Ian Cooke in Sheffield, before moving to Bristol to do his IVF training under Professor Michael Hull. He completed his subspecialty training in Cambridge and was appointed consultant there. He led on setting up Cambridge IVF and was its Person Responsible till 2014. He subsequently moved to Manchester and now leads one of the largest NHS assisted conception services. He is the BFS lead for Policy and Practice.

Fertility horizon scanning

Yacoub Khalaf

The field of assisted reproduction is ever changing with new developments being introduced frequently. Each intervention or finding creates with it a debate about whether it is effective and or indeed cost effective to adopt. Some interventions create ethical debates that can only be appropriate if it is supported by the right information. In this lecture recent clinical advances in assisted reproduction will be presented with an appraisal of what is known and what is yet to be known about them. The difference between biological plausibility and evidence of clinical effectiveness will be highlighted and their relationship to evidence based practice will be discussed.

Biography see page 6

Strategic tools for management

Jonathan Koslover

Key Learning Points: **TO BE ADDED**

Legal and reputational risk in assisted conception

Antonia Foster TO BE ADDED

Public relations and issues management

Claudia Rubin

Key Learning Points:

1. Since fertility treatment is an area of high and increasing public and therefore media interest, it is wise to have plans in place should positive or negative attention come your way.
2. Make few assumptions about other people's level of knowledge, understanding and sympathies
3. Be clear of the facts, the evidence, your position and stick to these.

Claudia's presentation looks at how fertility services can be perceived in the public domain and what issues service providers may face in this regard. With the growth of the global fertility services market and against a backdrop in the UK of an NHS under pressure, there is an inevitable higher level of interest from media and public organisations in your work. Increasing the skills and knowledge of all actors and stakeholders in this field will help you actively to defend and promote what you do so that more people can receive effective care and treatment.

Claudia Rubin is an experienced government affairs professional and communications strategist. She develops public policy programmes including parliamentary advocacy and stakeholder engagement for the health sector. Claudia's background is in the not-for profit sector where her understanding of the issues surrounding the NHS was formed, and she now works with many patient groups helping them to engage effectively with health policy. She is a Director at Decideum, a specialist public affairs and market access consultancy, which has worked for many years with Fertility Fairness (formerly NIAC).

BFS PARALLEL SESSION

The UK fertility market - understanding NHS commissioning and the private market

Charles Kingsland

Key Learning Points:

1. NHS funding for IVF remains a low priority.
2. Most of the time, Commissioners don't know what they are purchasing
3. Be innovative

Fertility therapy remains a high profile but very low priority service as far as the NHS is concerned. It is therefore important to form strong links with your local Clinical Commissioning Groups and try and support them with their decision making. Make it clear what they are purchasing and offer them value for money.

Charles Kingsland is Professor of Reproductive Medicine at The Post Graduate Medical Institute, University of Edge Hill. He is also a Consultant at IVI UK. Previously he was Founder of the Hewitt Fertility Centre and was for over 25 years its Clinical Lead. He was personally responsible for the creation of what is now the United Kingdom's largest NHS funded IVF service. The private income received from patients not eligible for NHS treatment was redirected into the Liverpool Women's Hospital enabling it to remain an independent Foundation Trust Hospital and one of only two hospitals remaining in the Country dedicated exclusively to the care of women and their babies.

How does the Quality Manager establish an effective quality management system?

Nilendran Prathalingam

Key Learning Points:

1. Basic understanding of the regulatory landscape governing fertility treatment.
2. What is Quality Management within a Fertility Centre.
3. An understanding of ISO and how it fits into a clinical and laboratory setting.

A Quality Management System (QMS) is vital to both the laboratory and clinical aspects of a Fertility Centre in order for the Centre to be safe and effective. Good document control, training programmes and selecting the correct key performance indicators and audits are vital. To be effective all staff have to be involved in the QMS and to see the benefits from the system. This presentation will use real life examples to demonstrate the importance of an effective QMS.

Nilendran Prathalingam is the Quality Development Manager at the Newcastle Fertility Centre. Having completed his first postdoctoral position in London, he joined the Centre in 2006 as a Postdoctoral Research Associate to derive clinical grade human embryonic stem cells. During this period he gained invaluable experience in Quality Management Systems in both a clinical and research environment. At the end of the project in 2012, he became the Quality Development Manager for the Fertility Centre. In this role he has prepared the department for numerous clinical and research HFEA inspections and works closely with the NHS Trust to meet their clinical governance requirements.

Establishing a robust performance enhancing appraisals framework

Raj Mathur

Key Learning Points:

1. What is appraisal and how does medical appraisal differ from other types?
2. What is the purpose of appraisal - support the individual or achieve organisational goals - both aims should be satisfied.
3. What are the pitfalls of appraisal, and how to avoid them.

Establishing a satisfactory appraisal framework requires an understanding of the types, purpose and pitfalls of appraisal. Medical appraisal must conform to GMC requirements and is primarily focused on identifying development needs of the individual and confirming competent and safe practice. In commercial settings, appraisal is more often about the goals of the organisation and the extent to which the individual helps achieve these. resources of time, expertise and space are needed, along with an organisational culture that supports individuals while also protecting standards and protecting patients. Appraisal should be kept distinct from the disciplinary process and not be undertaken with punitive intent. Appraisers should be conscious of the potential of unconscious bias, both positive and negative, which can damage the effectiveness and validity of appraisal.

Biography see page 10

ACE PARALLEL SESSION

Selecting the best statistical test for your dataset (interactive session) Interpreting data and presentation of results

Christine Leary

Key Learning Points:

A basic understanding / appreciation of;

1. How to deal with numeric and categorical data
2. How to choose between parametric and non-parametric tests
3. How to deal with multiple data sets and use of post-hoc testing

The application and appraisal of the use of statistical methodology is regarded by many scientists and clinicians as a daunting prospect. Most profess a familiarity with basic descriptive statistics and the identification of a significant p-value (<0.05), but falter at the application of more complex statistical software and use of models. However, a few simple considerations can aid in the selection of an appropriate statistical method and these will be illustrated via the use of examples specific to embryological / clinical data.

It is important to plan a statistical approach prior to starting a study, and this will be determined by the type of research question being asked, which will in turn inform the type of data to be collected, the possible groupings and necessary sample size. A key is to begin by defining the population, the intervention, comparator and outcome (PICO). Only when clear about the primary outcome and how it will be compared can one begin to think about the data type (numerical, ordinal, nominal), the likely distribution (normal, equal/ unequal variance) and the possible sources of bias which will need to be controlled for in the study design or in statistical tests.

For example, if the aim of the study is to determine a difference between groups, it is important to determine if the data sets are to be regarded as paired or unpaired and if the intervention could result in a deviation from the null hypothesis in either direction (1-tail or 2-tail). Moreover, different tests are required for continuous data or categorical data and it will be important to decide if the data meet the assumptions appropriate for the use of parametric or non-parametric test methods. Furthermore, if comparing more than two sets of data, a multiple group comparison test should be used first, followed by a post hoc test, if a significant p-value is returned.

If the aim of the study is to assess for an association between variables, a correlation coefficient test expresses the strength of the association and if variables have a linear relationship univariate or multivariate linear regression analysis can be applied. In the case of a binary dependent variable, logistic regression associations can be expressed as adjusted odds ratios. If in doubt about which methodology to apply it is important to seek the advice of a statistician. Statistics provide reassurance to hypothesis testing, however statistical significance is not necessarily the same as clinical significance and the interpretation of the data should be set within the context of other relevant studies.

Christine Leary (BSc, HCPC, FRCPath, PhD) is not a statistician, but has had call to use statistics during her scientific research and clinical embryological career. She is a Consultant Embryologist and Director at the Hull IVF Unit, with over 15 years' of experience and is responsible for managing the Embryology Laboratory and Quality Management. In 2013, Christine became a Fellow of the Royal College of Pathologists and she has recently completed a Doctoral thesis on the effects of maternal overweight and obesity on the viability and metabolism of human oocytes and embryos. Christine currently holds a number of additional positions and is a Teaching Fellow at the Hull York Medical School, an Executive Committee member of the British Fertility Society and a Professional Development Committee member for the Association of Clinical Embryologists.