British Fertility Society

Response to the

Department of Health

Consultation on proposals to transfer functions from the Human Fertilisation and Embryology Authority and the Human Tissue Authority

28 September 2012

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INTRODUCTION

1. This document represents the response of the British Fertility Society (BFS) to the Department of Health consultation on proposals to transfer functions from the Human Fertilisation and Embryology Authority (HFEA) and the Human Tissue Authority (HTA).

2. The British Fertility Society is a multi-disciplinary organisation representing professionals with an interest in reproductive medicine. The objectives of the society are to:

   - Promote high quality practice in the provision of fertility treatment;
   - Provide a common forum for members of various disciplines having an interest in the science and treatment of infertility;
   - Promote high quality scientific and clinical research in the causes and treatment of infertility;
   - Provide professional leadership in the provision and regulation of infertility services; and
   - Promote the increase of NHS funding for and equity of access to fertility treatments.

3. The regulation of assisted conception is therefore of interest to members of the BFS, and our comments are limited to the proposals on the future of the HFEA.

4. This document has been prepared by The Executive Officers and is submitted by the BFS Honorary Chairman whose contact details are:

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5. Further information on the BFS and the process followed in the compilation of this response is an Appendix.

OVERVIEW

Key Considerations

6. In compiling this response, the BFS has been guided by the following:

- The strong support of BFS members for the provisions of the HFE Acts and the importance of regulation in this area and an expectation that the level of regulation will remain the same;

- The fact that many BFS members believe that routine IVF is now well established in clinical practice and therefore should be regulated no differently from other medical procedures;

- The evidence that a dedicated regulator for IVF – a well-established, routine procedure, operated to high standards of quality and safety – is no longer justified and may be detrimental to good medical and laboratory practice;

- The recognition by BFS members that the regulation of embryo research needs some specific oversight to recognise the "special status" of the human embryo;

- That many BFS members involved in embryo research, suggest that a 'one-stop shop' is needed to replace the current system which requires researchers to go through different routes to obtain ethical approval and a research license – a system which is unnecessarily complex and inhibits embryo research in the UK;

- That before decisions are taken on the best location for the Register of Assisted Conception Treatment, an urgent review is needed to deliver a more streamlined data collection system;

- That the establishment of CQC and the HRA, provides the scope to simplify the current over complex regulatory enforcement framework to the benefit of patients, researchers and practitioners (a key aim of the Coalition Government);

- That BFS support for change is heavily dependent on the effectiveness of the regulatory frameworks established by the CQC and the HRA and on the process for managing the transition, areas not addressed in the consultation document.

7. These considerations are described more fully in the following sections.

The Legal Framework for Assisted Conception in the UK

8. The Human Fertilisation and Embryology Act 1990 and its revision of 2008 has been instrumental in providing clarity and assurance to patients, researchers, the medical profession, and the public about the practice of ART and embryo research in the UK. In addition, the EU Tissues and Cells Directive set standards for quality and safety to minimise risks of errors, contamination, and accidents in the laboratory, and these requirements are incorporated into UK law.

9. BFS members fully support the current legislative framework and the need for regulation in this area, which is essential to the continued maintenance of patient and public confidence. They also recognise the part that the Human Fertilisation and Embryology Authority (HFEA) has played in establishing a credible regulatory framework and providing high quality information for patients. However, many BFS members believe that the continuance of the HFEA as a stand-alone regulator of assisted conception and embryo research can no longer be justified, and may have unwanted adverse effects in marginalising the sector, as well as creating inefficiencies. The proposed transfer of functions to the Care Quality Commission (CQC) and the Health Research Authority (HRA) is an opportunity to alleviate these effects.

10. It is commonly suggested, not least by the HFEA, that the 'HFEA brand' is essential to public and patient confidence in the sector. Many BFS members have stated that it feels more credible to suggest that the current high reputation of the sector is due to the strength of the legislative framework and the direct experience of patients receiving high quality treatments. Regulation plays a part in this, but in other European countries with a thriving sector this is provided by a generic healthcare regulator. The BFS would contend that it is the Act that has established Britain's reputation worldwide and has been imitated elsewhere, rather than the HFEA, which hasn't.

The Regulation of IVF in the UK

11. There are good reasons why IVF has been regulated by the HFEA to date, including the ethical and moral sensitivity surrounding it in the 1980s and 1990s, the limited knowledge of risks and adverse outcomes and anxiety about the welfare of children born through IVF. On the whole, the HFEA has addressed these issues well. However, BFS members have now provided a number of arguments that support the need for change in the way the sector is regulated.

The Case for Mainstreaming Regulation

12. IVF is now a well-established procedure in the UK and worldwide. This is well illustrated by the following table extracted from data produced by the European Society for Human Reproduction and Embryology (ESHRE).

Table 1: ART in European in selected European countries in 2008[1]

Country	Cycles/million women 15-45	Cycles/million population	% Newborns Conceived through ART
United Kingdom	4066	825	1.9
Belgium	13069	2687	3.9
Denmark	12712	2450	4.6
Finland	9291	1698	3.1
Norway	9287	1778	-
Sweden	9288	1751	3.3
The Netherlands	6382	1290	2.4

13. It should be noted that there are less cycles of treatment carried out in the UK per head of population, and a lower percentage of newborns conceived through IVF, than in a number of other European countries with comparable ethical approaches. There is also no evidence of increased risk in these countries. Indeed, the HFEA has cited Scandinavia as a model of good practice in relation to elective single embryo transfer.

14. This demonstrates that IVF is flourishing in parts of Europe in the absence of a specialist regulator and casts doubt on claims that HFEA's regulatory oversight is essential to confidence in the UK sector.

15. Many BFS members feel that the creation of the HFEA, with its broad range of responsibilities was very much a reaction to the concerns of the day. It is very unlikely that a specialist regulator for IVF would be established today given the everyday medical nature of the treatments and the Government's clear emphasis on streamlining regulation.

16. There are also significant downsides to separate regulation of IVF. These include costly regulatory overlap between the HFEA and the CQC and a less immediately obvious marginalising effect on both patients and staff, particularly in (but not limited to) NHS organisations.

Regulatory Overlap

17. Both private and NHS clinics licensed by HFEA and registered with CQC have reported to the BFS significant duplication between the two regulators. One clinic estimated the overlap to be as much as 60-70%. Examples of overlap at inspection include the Quality Management System, complaints, incidents, audit, staff competency and training, staff interviews and patient interviews. This is unnecessarily disruptive and costly to clinics (many of which are Small and Medium Enterprises (SMEs)). The same clinic was inspected by both regulators with only a 5-6 month interval.

[1] Ferraretti AP, Goossens V, de Mouzon J, Bhattacharya S, Castilla JA, Korsak V, Kupka M, Hum Reprod. 2012 Sep;27(9):2571-2584. Epub 2012 Jul 10

18. Of course BFS members recognise that the focus of the two regulators is different but there is also considerable cross over. CQC inspection is generally patient centred, and emphasis is placed on patient pathway, care and facility. The HFEA's focus is on embryology and laboratory practice. However, the clinics who have spoken with BFS, report that both HFEA and CQC have covered consent, patient treatment and the provision of treatment and outcomes information. Both regulators interview patients and staff, both employ very similar processes of self-assessment against standards and both require similar evidence in support.

19. Both the HFEA and the CQC operate incident reporting systems, creating further duplication through two separate reporting routes. The HFEA require reporting of incidents relating to loss or damage to embryos, hospitalisations and breaches of confidentiality. CQC may also require some of these to be reported to them but their main interest is in any significant incidents that happen to patients whilst in the care of clinics.

20. It seems self-evident to many BFS members that there are clear synergies between the CQC and the HFEA on regulatory and licensing functions. In particular, the six main areas of the CQC's Essential Standards of Safety and Quality are equally relevant to assisted conception:

    - *Personalised care, treatment and support* – individual needs, health promotion, day to day care;
    - *Involvement and information* – appropriate information giving methods, consent forms;
    - *Quality and Management* – internal control, complaints, incidents, records;
    - *Suitability of staffing* – recruitment, qualifications, training, manpower;
    - *Suitability of management* – capability, structure, monitoring, finance;
    - *Safeguarding and safety* – facilities, standard operating procedures, medicine, equipment;

21. The HFEA has acknowledged that unnecessary regulatory overlap is a burden (although they do no acknowledge its extent) and have a commitment with CQC to coordinate activities better through greater partnership, with the objective of introducing a single regulatory regime for assisted reproduction centres. This is welcome, but it will do nothing to address the problems of marginalisation described in the next section.

The Benefits of Integration

22. Effective regulation should provide a lever for improvement to the benefit of patients, for example by lending support to a case for extra resources on staffing or training. However, the consistent experience of many BFS members working in NHS IVF clinics is that this does not happen.

"Over the past few years, I have conducted investigations on behalf of a number of large NHS hospitals where a common contributory factor to the problem appeared to be a lack of engagement by hospital management because they saw the assisted conception service was regulated differently and there was a sense that they were excluded because it was not seen as part of their domain."

Dr. Allan Pacey, University of Sheffield.

23. BFS members have reported that regulating IVF separately from other types of mainstream healthcare has led to a culture in which IVF patients within an NHS setting are seen as different from the general patient population. The impact, in large NHS organisations, is that senior management and Board members display limited or no interest in the HFEA inspection process or outcomes in stark contrast to the priority given by Trust Boards to the outcome of CQC inspections. Integration of IVF/assisted conception into a single process of registration and regulation would ensure the Executive level responsibility and Board level accountability applicable to all other acute services. This would facilitate greater executive level ownership of the quality and safety standards that pertain to this area of clinical practice.

24. The generic systems of audit and governance that apply to the safety and quality of clinical practice in other areas of complex medical interventions for example blood transfusion, transplantation, major trauma and intensive care are equally applicable to assisted conception. Many BFS members have argued that integration of regulation under the CQC would be a key enabler for assisted conception services to benefit from these systems and more importantly their supporting infrastructure and the accountability framework that underpins them.

IVF treatment is an established part of clinical practice and has been undertaken for over thirty years. Whilst its social profile is not doubted and the specifics of gamete and embryo handling require particular expertise, generic systems of quality and safety used in other areas of clinical and laboratory practice are equally applicable to assisted conception. The continued consideration of ART as a unique and discrete area for the purposes of regulation and quality assurance is neither necessary nor best serves the interests of patient care"

Richard Kennedy, Medical Director at UHCW NHS Trust

25. All BFS members believe that a regulatory regime should bring clear benefits to IVF patients. They should not be stigmatised by being seen as 'different'. Were we starting today with a blank sheet of paper, we would be designing a single healthcare regulator that included assisted conception. Many BFS members are of the opinion that we now have an opportunity to bring regulation of IVF into the modern age through the proposed transfer of the HFEA's functions to CQC. This is reinforced by

considerable scepticism about whether the level of change needed can be achieved whilst keeping the HFEA as a stand-alone regulator.

Arguments for Retaining the HFEA

26. There has been an active debate within the BFS membership, and with other stakeholders, about the case for retaining the HFEA. Some BFS members would prefer to see the HFEA retained, although the need for further efficiencies is recognised by almost all. The complete absence of proposals in the consultation document about how regulation of the sector would operate post HFEA has made it difficult to give whole hearted support to any option. And the concerns raised by the Public Accounts Committee among others about the readiness of CQC to take on additional functions, raise questions at the very least about the proposed timetable for change.

27. Nonetheless, many BFS members consider the arguments deployed for retaining the HFEA to be seriously flawed.

Risks & Incidents

28. In her evidence to the Public Accounts Committee on 25 January 2012, arguing the case for retaining the HFEA, the HFEA Chair, Lisa Jardine described IVF as "the sharp pointy end of risk in our society". She went on to say that "By the time there has been an incident in IVF there is a baby in the wrong mother or a baby with the wrong donor…. The public believe we [the HFEA] regulate in such a way that this is unlikely to happen" [2]

29. Incidents in IVF are in fact very rare. Following an incident in Wales in 2009, in which a couple were told that their last frozen embryo had been mistakenly implanted into another patient, Alan Doran, then Chief Executive of the HFEA, put the issue of incidents into proportion:

> *"Out of more than 50,000 cycles of treatment, 0.5 per cent resulted in an incident. Very few of these incidents are as serious as the one at IVF Wales. It is impossible to eliminate human error. We strongly encourage clinics to report all incidents and near misses, so that we can help them learn from their mistakes and to spread best practice across the sector."*

30. There will always be adverse incidents in healthcare, but these are no more likely to occur in the IVF clinic than elsewhere. Risks in IVF are now well understood by practitioners, explained to patients and well managed with professional bodies (eg the British Fertility Society, the Association of Clinical Embryologists etc) who publish guidelines for good practice as well as provide education and training of persons engaged in the profession.

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[2] House of Commons Committee of Public Accounts: The Care Quality Commission: Regulating the quality and safety of health and adult social care. Seventy-eighth Report of Session 2010–12 HC 1779

31. When the HFEA was first established, hospitals did not have the same level of clinical governance as they do today. In addition, in assisted conception units, there is a strong focus on ISO quality management systems and strategies for improving patient safety. This includes assessing how patients could be harmed, preventing or managing risks, reporting and analysing incidents, learning from such incidents and implementing solutions to minimise the likelihood of them reoccurring. As mentioned at paragraph 19 above, CQC already has an incident reporting system in place. Merging this with the system currently run by the HFEA would both remove duplication and provide an equivalent level of assurance to patients.

Patient Confidence

32. Patient confidence stems from the protections in the HFE Act and patients' direct experience of clinics providing high quality, patient-centred, care. It is not linked to the identity of the regulator. It is the view of many BFS members that patients associate the HFEA 'brand' with the HFEA's per cycle fee and with the 'find a clinic' facility on the HFEA's website, but little else. They want to know that there is regulation, but there is no evidence to suggest that they will lose confidence if regulation is provided by CQC. The fact is that 90% of HFEA licensed clinics in England are already registered with CQC, with CQC already proving a focus on patient safety and quality.

33. As shown in Table 1 above, the assisted conception sector is thriving in Scandinavia and elsewhere in Europe, with regulation under the European Tissue and Cells Directive provided by generic regulators. In Denmark, which has the highest percentage of newborns conceived through ART, the Danish Medicines Agency took on the role of competent authority under the EU Tissue and Cells Directive. In March 2012, this merged with the Danish National Board of Health to form the Danish Health and Medicines Authority, of which inspection and licensing of assisted conception clinics is one small element.

Loss of Expertise

34. As acknowledged in the DH Impact Assessment, some BFS members are concerned that the transfer of HFEA functions to the CQC may result in a loss of expertise. However to others this feels like a non-issue as most HFEA staff will follow the transfer of work. CQC staff are also expert in standards-based inspection processes. Avoiding loss of expertise should be a priority for those managing the transition but is not a strong argument against change.

Provision of Ethical and Policy Advice

35. This is addressed in more detail at paragraphs 70-74 below. Rather than seeing the continuance of the HFEA as necessary to address future policy and ethical issues surrounding assisted conception, there is a strong

argument for these to be considered in a broader forum than the HFEA. Regulatory policy issues would naturally fall to the CQC, as they do at present.

Competence of the CQC

36. This is a shared concern of many BFS members, which needs to be taken seriously by DH. However, the majority of clinics we have spoken to who are registered with the CQC have confidence in the rigour of their inspection processes. The real issue, as with any organisational merger, is the effectiveness of how the transition is managed in practice (see paragraph 75 below). Some BFS members have expressed concern that the CQC does not have competence in the inspection of laboratories. However, we would expect that, in taking on the HFEA's functions, the CQC would engage staff with this expertise from the HFEA or elsewhere

Readiness of the HFEA to Make Changes

37. As noted in paragraph 25 above, many BFS members are sceptical about whether the level of change that the HFEA needs to deliver can be achieved whilst keeping the HFEA as a stand-alone regulator. We note that the HFEA say that they have put in place an efficiency programme that has reduced their costs by 30% since 2009 and have plans to make further savings. However, these savings have happened only as a result of the pressures brought about by the Arms' Length Body Review. Moreover, the BFS has been concerned that some of these efficiencies have had little impact in clinics and patients given the £3.4M HFEA cash surplus reported in the press in February 2012.

38. Were option 3 of the consultation proposals implemented, it is hard to see where the impetus for further change would come from. In dialogue with the HFEA the BFS has over the years suggested efficiencies to aspects of regulation, including (i) the regulation of embryo research; (ii) the process and extent of data collection; (iii) the provision of information to donor conceived people; (iv) concerns about 'regulatory creep'; and (v) the development of standards and policy. However, largely these suggestions have fallen on deaf ears.

The Regulation of Embryo Research

Background

39. There are currently 23 active research licences awarded by the HFEA in 17 Centres. Approximately eleven are related to the derivation of embryonic stem cells from embryos, four to embryo culture, three to preimplantation genetic diagnosis, two to the fertilisation process, one for chromosomal analysis of embryos, one for vitrification techniques and one for research on hybrid embryos. There are no applications pending. Only

two licences are for private/commercial centres: the remainder are from established academic departments. Fourteen of the centres that hold a current licence also held a licence in 1994. Thus they have had successful annual inspections/reports for 16 years. The typical profile of a centre undertaking embryo based research in the UK is a University linked department with a longstanding record of successful progress in this field and a low risk assessment by the HFEA.

40. By comparison, NRES currently receives about 500 applications a month. The scale of embryo research in the UK is thus relatively very small.

41. Prior to the Human Fertilisation and Embryology (1990) Act, medical research (including research involving human embryos), was conducted following approval from a local research ethics committee and with funding from bodies like the Medical Research Council (i.e. they would not fund unethical research).

42. In 1991, local research ethics committees were newly established and were largely autonomous bodies and arguably did not have the appropriate skill to enact the legal requirements of licensing research on human embryos in the HFE (1990) Act. Therefore, from 1991 onward it was wholly appropriate that the HFEA should take on the function of licensing research on human embryos and therefore providing support to local research ethics committees to approve medical research in this area.

43. The extent to which the HFEA was efficient and effective in its licensing of human embryo research during this time is a matter of debate to many BFS members involved in research. However, although the regulatory system for approving medical research in the UK developed enormously, the licensing of human embryo research did not. By the year 2000, and the establishment of the Central Office for Research Ethics Committees (COREC), researchers wishing to use human embryos in research had to manage two very different and sometimes contradictory systems in order to achieve this. This included, and still includes, two different application forms, documents such as protocols and CVs being requested in different formats. Similarly, throughout the research, separate progress reports and final reports had to be submitted to different timescales and in different formats, leading to an inevitable duplication of effort.

44. Some researchers have reported to the BFS that they have chosen not to propose projects using human embryos because of the unnecessary complexity of obtaining ethical approval and a research license through different routes. There is evidence to suggest that this bureaucratic complexity has inhibited rather than enabled the UK to be at the forefront of medical research involving human embryos.

"There are too many regulatory authorities for stem cell research including the HFEA and therefore consolidation of the regulators will in the long run be important to remove barriers for development of

regenerative medicine applications. For human embryo research I do think this responsibility would be better with not being within the HFEA as investigations for using human embryos in research has broadened over the years and would be better served by a body with a broader remit and viewpoint. However it will be important that patients have confidence that if they donate their embryos for research that there is proper oversight."

Professor Harry Moore, Department of Biomedical Science, The University of Sheffield

45. The BFS has heard from one researcher that the involvement of the HFEA in regulating research is having negative effects on the ethical review system:

"The current system of duplication undermines the ethical review system such that ethics committees which are properly constituted may defer to the judgement of the HFEA rather than give applications full independent scrutiny"

Professor Richard Anderson, University of Edinburgh

46. In recent years, the national research infrastructure has been strengthened with the establishment of the National Research Ethics Service (NRES) in 2007 and, following the report by the Academy of Medical Sciences in January 2012, the establishment of a new independent Health Research Agency (HRA).

The Health Research Authority

47. After reading the arguments in the consultation document, the majority of BFS members support the proposal to transfer to the HRA the HFEA functions relating to research other than inspection.

48. This support is contingent on an understanding that a way will be found to create a 'one stop shop' for all research applications to put an end to the damaging bureaucratic complexities of the current system. This should start with a single application and conclude with a single approval.

49. The BFS believes that the IRAS application system is sufficiently generic to allow the integration of key questions about any embryo research that will then initiate 'behind the scenes' action by the HRA to assess these applications, perhaps by one or two ethics committees that have received specific training and have the specific support to do so.

50. The BFS first proposed this idea in 2005 (using the then COREC form) and it is disappointing that this was never taken forward.

NRES Consideration

51. The BFS understands that NRES research ethics committees already consider research outside the NHS where the law requires it. For example research involving patients who lack capacity to give informed consent or research involving ionising radiation. There would therefore be nothing to prevent embryo research applications being considered by NRES committees.

52. The requirement for embryo research applications to be considered by a local research ethics committee is a HFEA policy requirement and in retaining the safeguards, we understand that DH would expect HRA to continue to require review by a research ethics committee using NRES research ethics committees.

Inspection and Licensing

53. The BFS understands that the HRA would not wish to undertake the inspection of embryo research laboratories as they do not have this expertise. Most BFS members would support the transfer of this function to the CQC or to another appropriate body. This has the advantage of reducing possible fragmentation in the system.

54. Because the inspection process for centres engaged in embryo research is not specific - it follows the general principles of quality management - it could be undertaken by anyone with appropriate inspection skills

55. The HFEA has said in its response to the consultation that:

    "..regulatory processes and legislation that govern embryo research in the UK are necessarily dependent on those governing fertility treatment; as the majority of embryos used for research in the UK are donated by couples undergoing fertility treatment…..As such, there is merit in having a single integrated licensing regime which governs the processes by which all gametes and embryos can be procured; the length of time for which they can be stored; and which ensures that appropriate information is provided to embryo donors and that all required consents are in place before embryos can be used in research."

    It should be noted that the need for a link between clinical and research regulation does not apply to other areas of medical research. Some BFS members have commented that in practice the HFEA is rigid in ensuring that there is separation of research and clinical practice with, for instance, strict rules on clinicians who undertake research not being involved with that patients' clinical treatment. The 'continuity' link is an idea that the HFEA has often quoted but has no ethical or practical foundation elsewhere.

56. The HFEA has also suggested that there would be an increase in inspections if research functions were transferred to the HRA. However, although the HFEA usually now carries out treatment and research licence inspections at the same time, the processes are in fact completely

separate. Separate documentation is required, different personnel are involved, there are different reports and different licence committee decisions to respond to. BFS members would therefore challenge the HFEA's assertion that transfer of functions to the HRA "would make the regulatory regime more complex (and duplicate administrative costs) not less."

"Embryo based research in the UK appears to be flourishing because of a `very small number of high profile projects. Clinical embryology research is minimal and insignificant in the international context. In the NICE Guidelines on Fertility 2004, of the 100 areas of practice reviewed only one related to an embryology procedure (assisted hatching). The literature on assisted hatching was reviewed by a Manchester group in 2003. It contained 23 randomised trials, all of which were outside the UK. The lack of research in clinical embryology is regrettable. It does not appear to be because of a lack of interest by UK practitioners but is certainly not encouraged by the regulatory environment."

Professor Alison Murdoch, Newcastle University

The Register of Assisted Conception Information

57. The key issue for the BFS is the need for simplification of the process for collection of data and an end to the collection of information by the regulator which is not needed either for regulatory purposes or to meet the requirements of the HFE Act.

58. The requirements for the Register of Information are set out in the HFE Act and there is a duty on the HFEA to hold this information. There is currently no clear remit to provide feedback to clinics, and the database to which individual clinics contribute is not readily interrogated by them. The HFEA has however made some moves very recently to provide centres with individualised "profiles" and recommendations with regard to success rates and multiple births. However, this has not been welcomed by all BFS members who cite this as an example of ongoing 'regulatory creep':

"The HFEA now includes clinical performance, in terms of pregnancy rates as part of their quality assessment, and intends to notify clinics if their rates drift outside the expected ranges. This is not useful to centres, who are required to monitor their key performance indicators as part of their quality systems, and who are therefore likely to have this information before they are informed by the HFEA. Moreover Centres will be expected to provide a plan to the HFEA as to how they intend to address such a problem, despite the fact that the HFEA is not an expert body, and therefore not qualified to comment on the likely efficacy, or appropriateness of any plan. This is not only unhelpful, but also puts further negative pressure on centres, and is a prime example of regulatory creep, as there is nowhere in statute, or the regulatory framework that suggest or implies this is part of the remit of the regulator."

Dr Sue Avery, Director of Assisted Conception, Birmingham Women's Healthcare Trust

59. The BFS has identified a number of systemic faults with the Register that have evolved over the years, and along with other stakeholders proposes a major review of its content and structure. This has been written up as a publication currently under review and a draft copy is attached to this response for information.

60. Some of the recommendations made about the register are consistent with current practice but some will require fundamental changes. This includes:

- *Simplifying the reporting and recording of data* For a single treatment cycle, it is currently necessary to complete and submit up to 6 separate data forms to the HFEA. All clinics use a single record for each patient/treatment provided. This mismatch of data recording is unnecessarily complicated and it would be more appropriate if data were held by the HFEA and clinics in a similar format.

- *Taking full advantage of electronic technology*. For instance, separate forms are needed for donor insemination and IVF treatments and for treatment outcomes. The advantage of digital technology is that a single database format can be created that can be used to input data from all treatment types. This would use 'drop-down' choices since most fields contain mutually exclusive entry options. This single form would include all the data needed for each treatment.

- *Removing inconsistencies between different licensed treatments*: The data collection processes have evolved over many years. This has not always been associated with transparent explanation or consistency. For instance, in 2009, following the inclusion of gamete "processing" into the portfolio of licensed procedures, new forms were introduced relating to sperm processing for insemination and gamete intrafallopian transfer using partners sperm. Although this requirement also led to the need for some unlicensed centres to apply for and attain HFEA license, the data collection is a simple annualised form relating to cycle numbers and success rates. No patient identifying information is requested. This brings into focus the inconsistency in data collection between licenced treatments and demonstrates the need to review.

- *Addressing regulatory creep* Over recent years the HFEA has expected clinics to complete various new forms, sometimes unheralded (e.g. monthly donor sperm procurement form) and without any clear explanation of why the information is sought. The implications for clinics are not taken into account other than a

presumption that if the HFEA asks for data then data must be supplied.

61. The BFS has identified savings that could be achieved through an improved data collection process and would expect to see these passed back to the clinic as a fee reduction. It is noteworthy that these discussions began over 10 years ago but during that time the data collection has continued expanding much to the frustration of many BFS members. One clinic has calculated recently that staff spent a staggering total of 5 hours 20 minutes inputting data on the HFEA's electronic data collection system (EDI) during just one cycle of a single patient's successful treatment.

62. BFS would support the siting of a reformed Register either by the CQC or by the NHS Information Centre (IC). The arguments given in the consultation document for transferring ownership of the Register to the IC are compelling, but we do not know enough about the IC to say if this is workable. The question of who maintains the Register is less critical to BFS than having an effective Register that is fit for purpose.

63. We have discussed options for siting the Register with NHS Connecting for Health, and recommend that DH does the same. Possible solutions could involve overall management of the Register by the National Back Office, who already handle very sensitive data, (eg witness protection information and the database of HIV infected individuals), and the IC who could hold the data and bring to bear their expertise in managing large databases and in data analysis. An options appraisal may be the best way forward.

64. There is also a strong case for developing an information standard for the Register. This would be a formal document approved and issued by the Information Standards Board for Health and Social Care, defining technical criteria, content, methods, processes and practices. Information standards are helpful in giving assurance on the management and use of databases, and can be particularly valuable where data is sensitive. For example, a standard is currently being developed for the HIV and AIDS Reporting System.

Information to Donors and Donor Conceived People

65. Many BFS members support the view in the consultation document that the provision information to donors and donor conceived people is not a regulatory activity and therefore does not belong with either the HFEA or the CQC.

66. The view of most BFS members is that this should instead be a fully professional service, providing mediation and origin counselling similar to that established in post adoption services. This was first suggested by the

BFS in 2005 following the announcement about the removal of donor anonymity:

"The BFS believes it is essential that clinics are able to inform donors about the likely route by which donor conceived people may make contact with them. It is disappointed that the UK government currently has no plans to fund mediation and origin counselling similar to those established in post adoption services."[3]

67. Others have highlighted concerns about the HFEA's current approach:

> *"The current care that is given to post adoption services could be applied to post donation care – currently there is no clear pathway which has raised concerns amongst both patients and healthcare professionals. For example, I have worked as a counsellor seeing people who are considering gamete/embryo donation or offering to be donors for many years now as well as having active links with people who are donor conceived. These key stakeholders are increasingly sharing their concern about the inadequacy of the HFEA policy in relation to the collection of full biographical information about donors which fails to recognise that parents who want to share this information with their children from a young age need all the information requested of donors. The HFEA made a decision that only demographic and medical information was mandatory so that much of the information that children and parents need will be missing."*
>
> Jennie Hunt, Senior Accredited Member, British Infertility Counselling Association

68. BFS Members do not have strong views on which organisation would be best placed to run a Post Donation Care Service. DH may wish to consult BASW's Project Group on Assisted Reproduction (Progar) and/or the British Infertility Counselling Association (BICA) who are better placed than BFS to advise on this.

69. To avoid the risk of fragmentation, the contracting out of the Post Donation Care Service may be better undertaken by CQC than by DH. Care would need to be taken to ensure proper governance around the transfer of data, ensuring that people only see the information they need to know. However, there is no reason why this should not be technically possible.

Responsibility for Policy Development

70. The HFEA derives its policy role from two statutory functions in the HFE Act – a duty to advise the Secretary of State and a requirement to

[3] BFS Press Release: Fertility specialists welcome sperm and egg donor campaign but call for more action in time for change in law in April 2005, 26th January 2005

produce a Code of Practice (which by its nature requires the development of regulatory policy, eg advice on clinics on how to comply with the law and how compliance will be measured). Some BFS members have argued that the HFEA has gone beyond its statutory remit in developing policy in areas that relate to neither of these functions. The HFEA's work on donor remuneration and donor recruitment are two such examples of regulatory creep mentioned by BFS members.

71. The DH Arms' Length Body Report of 2010 makes clear that:

"Setting policy is the role of the Department of Health not arm's-length bodies, although arm's-length bodies will often have a role in policy development and implementation determined by the Department of Health"

72. Some BFS members argue that the HFEA is not an expert body and is not constituted as such. Nor is it appropriate for the HFEA as a regulator to make policy other than on regulatory issues, in the same way that we would not consider asking the police to make the law. There is a conflict in a situation where the body that has to implement the rules also makes them.

73. The House of Commons Science and Technology Committee inquiry into Human Reproductive Technology, which reported in March 2005, made a similar point:[4]

"…the current regulatory model, which provides the HFEA with a large amount of policymaking flexibility, should be replaced with a system which devolves clinical decision making and technical standards down to patients and professionals while at the same time strengthening Parliamentary and ethical oversight. Legislation should reflect the fact that assisted reproduction is now a standard clinical procedure and its focus should be on improving clinical standards and ensuring safety."

74. BFS members consider that the public interest in many of the policy and ethical issues currently considered by the HFEA, would be better and more democratically addressed through a properly constituted DH advisory group.

The Management of Change

75. This is a critical issue not addressed in the consultation document. Reponses from BFS members have shown that there is not enough information regarding the options that could be put in place, especially for the devolved governments. The absence of information about how the functions of the HFEA will be exercised by the CQC and the HRA, whilst

[4] House of Commons Science and Technology Committee: Human Reproductive Technologies and the Law, Fifth Report of Session 2004–05, Volume 1 HC 7-I

understandable, means that BFS support for the transfer of the HFEA's functions is contingent on a number of factors:

- that there is complete openness by the regulators around planning for the transition and that stakeholders are fully engaged in this process in line with Coalition objectives on government transparency.

- that expertise will follow function so that the CQC is properly equipped to take on HFEA functions that are new to it (eg inspection of IVF laboratories).

- that the transfer of HFEA functions to the CQC results in a single inspection leading to registration with the CQC that would include a licence for assisted conception.

- that a single fee is levied by CQC to cover registration and licensing.

- that the transfer of the HFEA's functions on licensing of embryo research will create a 'one stop shop' for all research applications.

- that the remit of the HRA will be extended to cover research licence applications from outside the NHS.

- that a major review of the Register of Information is undertaken and that cost savings are passed on to clinics.

- that the on-line Find a Clinic Guide continues under the new arrangements.

- that CQC engages stakeholders in the development and drafting of the Code of Practice required under the HFE Act.

- that a suitable provider will be found to undertake the provision of information to donors and donor conceived people.

- that, although the HFE Act is already UK law, proper account is taken by regulators of other relevant laws in devolved countries, for example Scottish family law.

RESPONSE TO THE CONSULTATION QUESTIONS

1. **Do you agree with the option to transfer all HFEA and HTA functions to CQC with the exception of HFEA functions relating to research that will transfer to the HRA and abolish the HFEA and HTA? Please explain why you think this.**

Yes. As discussed in the Overview section [paragraphs 11-25 above], many BFS members are of the opinion that:

- There are no compelling reasons to continue to regulate IVF as a distinct category of treatment, and some serious downsides to continuing to do so.

- There are good reasons why IVF has been regulated by the HFEA to date, including the ethical and moral sensitivity surrounding it in the 1980's and 90's, the limited knowledge of risks and adverse outcomes, and anxiety about the welfare of children born through IVF. Today, however, IVF is a well-established, routine medical procedure.

- Integration of regulation under the CQC would be a key enabler for assisted conception services to benefit from the generic systems of audit and governance that apply to the safety and quality of clinical practice in other areas of complex medical interventions and more importantly their supporting infrastructure and the accountability framework that underpins them. This would deliver considerable benefits to patients.

2. **Can you quantify what impact this could have at a local level (either in relation to service providers or patients or both)?**

<u>Transfer of functions to CQC</u>

- On the assumption that the transfer of HFEA's functions to the CQC will lead to combined inspections, there will be a reduction in burdens on clinics currently inspected by both. Current estimate is a 60-70% overlap for some clinics inspected by both HFEA and CQC. We cannot provide an estimated cost saving but would be happy to work with DH to quantify this. [see paragraphs 17-21above]

- For clinics that are part of larger NHS organisations, or large private organisations delivering a range of services, removal of separate regulation of assisted conception and a move to regulation by CQC will facilitate greater executive level ownership of the quality and safety standards that pertain to this area of clinical practice. Greater integration will ultimately lead to continued improvements in patient care. [see paragraphs 22-25 above]

Transfer of functions to HRA

- If, as hoped, this creates a 'one-stop shop' for approval for embryo researchers, the process for researchers will be simplified, removing a bureaucratic barrier to embryo research in the UK. [see paragraphs 47-56 above]

The Register of Assisted Conception Information

- The BFS has identified savings that could be achieved through an improved data collection process and is seeking a major review, with the resulting savings passed back to clinics as a fee reduction. [see paragraphs 57-64 above]

3. **Do you agree that HFEA functions relating to research should be transferred to the HRA? Please explain why you think this**.

Yes. The current system which requires researchers to go through different routes to obtain ethical approval and a research license is unnecessarily complex and inhibits embryo research in the UK. Most BFS members wish to see a 'one stop shop' for all research applications to put an end to the damaging bureaucratic complexities of the current system. There is evidence to suggest that the current system has inhibited rather than enabled the UK to be at the forefront of medical research involving human embryos.

The BFS believes that the IRAS application system is sufficiently generic to allow the integration of key questions about any embryo research that will then initiate 'behind the scenes' action by the HRA to assess these applications, perhaps by one or two ethics committees which have received specific training and have the specific support to do so. [see paragraphs 47-52 above]

The BFS understands that the HRA would not wish to undertake the inspection of embryo research laboratories as they do not have this expertise. BFS members would support the transfer of this function to the CQC or to another appropriate body. [see paragraphs 53-56 above]

4. **Do you think that some HFEA and HTA functions might sit better with bodies other than CQC and the HRA? If so, which functions and which organisations and what do you see as the advantages of the alternative organisation?**

Yes

There are two HFEA functions which many BFS members believe would sit better with other bodies:

The Provision of Information to Donors and Donor Conceived People

Many BFS members support the view in the consultation document that the provision information to donors and donor conceived people is not a regulatory activity and therefore does not belong with either the HFEA or the CQC. This should instead be a fully professional service, providing mediation and origin counselling similar to that established in post adoption services. [see paragraphs 65-69 above]

The Development of Policy and Ethical Opinion (other than Regulatory Policy)

Many BFS members argue that the HFEA is not an expert body and is not constituted as such. Nor is it appropriate for a regulator to make policy other than on regulatory issues, in the same way that we would not consider asking the police to make the law. There is a conflict in a situation where the body that has to implement the rules also makes them. BFS members consider that the public interest in many of the policy and ethical issues currently considered by the HFEA, would be better and more democratically addressed through a properly constituted DH advisory group. [see paragraphs 70-74 above]

5. **Do you believe the HFEA and HTA should retain existing functions but deliver further efficiencies? Please explain why you think this**.

No. We would have no confidence that the level of change called for would be delivered by HFEA if it retains its current functions. For some of the issues outlined above the BFS has a long history of dialogue and lobbying for change [see paragraphs 37-38 and paragraph 50 above] and this has largely fallen on deaf ears.

6. **Do you think that retaining functions with the HFEA and HTA could deliver savings to the public purse? If so, please explain how and quantify**.

Most BFS members remain sceptical that this would happen. In any case, as this response demonstrates, the case for change (especially the case for delivering benefits to patients by mainstreaming the regulation [see paragraphs 22-25 above] of assisted conception) goes beyond savings to the public purse. Many BFS members believe that this cannot be achieved while the HFEA is in existence.

7. **Within the option of retaining the HFEA and the HTA as independent regulators, are there any of their functions you think should be transferred elsewhere and, if so, which and why?**

Were the HFEA to be retained, many BFS members would still wish to see the transfer elsewhere of the HFEA's ethical and policy role and the function to provide information to donors and donor conceived people (see response to question 4 above). The majority of BFS members would also still wish to see a major review of data held on the Register and the transfer of the HFEA's embryo research functions, other than inspection, to the HRA.

8. **Do you have any comments on our assessment of the efficiencies associated with the different options in paragraphs 154-158 and in the accompanying consultation Impact Assessment?**

Paragraph 157 of the Impact Assessment states "The proposal to transfer HFEA and HTA licensing functions to CQC would, therefore, present CQC with the opportunity to make efficiency savings in terms of removing duplication of effort for both the regulator and providers in the assurance process. It would be for CQC to decide how it discharged any inherited functions."

BFS members would expect cost savings to be delivered to clinics through combined inspections. These need to be quantified.

We would also look to the HRA to deliver savings to researchers through the development of a 'one-stop shop' for submission of applications.

Additional efficiencies could also be achieved through the major review of the collection of data proposed by BFS and other stakeholders.

9. **This consultation focuses specifically on where functions might sit and implementation will be at the discretion of the regulators. However, if you have any views as to how functions might be undertaken in future or other issues of concern that we could share with the bodies undertaking these functions as they plan for the future, please let us know.**

There is a strong expectation on the part of BFS members that there must be complete openness by regulators around planning for implementation and that stakeholders must be fully engaged in this process in line with Coalition objectives on government transparency. BFS members also expect to see full stakeholder involvement in key areas such as the development of the Code of Practice required by the HFE Act.

In a situation where regulators will be taking on functions that are new to them, it is vital that expertise follows function. This is particularly essential in relation to the transfer of HFEA's expertise in inspection of laboratories.

However implementation is managed, BFS members expect to see properly integrated inspections and arrangements that bring together CQC registration and licensing of assisted conception.

BFS members also expect to see a single fee levied by the CQC to cover registration and licensing, although we recognise that this may not happen immediately.

A key priority in all of this should be to avoid fragmentation, for example by CQC undertaking inspections of both research and treatment centres, by managing the siting of the Register of Information and by managing the outsourcing of a Post Donation Care Service for donors and donor conceived people

10. **Do you have any other comments on the consultation proposals that you would like to share with us?**

Assuming a decision is taken to implement Option 1 or 2, BFS members would expect to see a further consultation with stakeholders on how a future model might work in practice. The BFS would be willing to work with DH along with other stakeholders to advise on the best way forward.

11. **Can you provide examples of costs and benefits of these proposals?**

This is not possible given the absence of detail about how these proposals might be implemented in practice. However, the BFS would be happy to contribute to further work on the impact assessment as plans develop.

12. **Do you have any comments on the consultation Equality Analysis?**

In line with the conclusions of the Equality Analysis, we are not aware of any impact that these proposals would have on the equality groups.

About the BFS

Background

1. With the encouragement of IVF pioneer Patrick Steptoe, the British Fertility Society was founded in 1972, by a small group with a common interest in infertility. Since then the burgeoning knowledge in this exciting area of medicine has resulted in the development and introduction of many new reproductive technologies and into clinical practice. The interests of the BFS have broadened to a range unimaginable 40 years ago. The British Fertility Society has grown alongside the development of our speciality and now actively promotes the sharing of knowledge, further education and raising standards of practice.

2. Today, the Society is the only professional body with multi-disciplinary membership across the medical and scientific practice of reproductive medicine. It welcomes andrologists, counsellors, embryologists, endocrinologists, nurses, and other professional groups working in this field, into its membership. At the end of 2011, the BFS had 899 members, comprising 404 clinicians, 129 Nurses, 100 scientists and a mixture of Counsellors, Students and Associates.

BFS Executive Committee

3. The activities of the BFS are directed by the Executive Committee, elected by the membership. A number of sub-committees have remit for specific areas, namely Training, Policy & Practice, Meetings, and Website. The Committees are held quarterly and report to the Annual General Meeting at the Annual BFS Meeting.

4. The current members of the Executive Committee are:

President	Mr Richard Kennedy
Chairperson	Dr Allan Pacey
Secretary	Mrs Alison McTavish
Treasurer	Dr Susan Avery

5. The current elected members of the Executive Committee are:

Andrologist Member	Mr Kevin McEleny
Clinician Member	Dr Jane Stewart
Clinician Member	Professor Adam Balen
Clinician Member	Mr Charles Kingsland
Counsellor Representative	Ms Ruth Wilde
DGH Member	Dr Valentine Akande
Embryologist Member	Dr Virginia Bolton
Junior Clinician Member	Mr Richard Russell

Nurse Member	Ms Trudi Campbell
Scientist Member	Dr Joyce Harper
Scientist Member	Professor Sheena Lewis
Nurse Member	Mrs Karen Woodcock

Initial BFS Response to the DH Consultation

6. Following the launch of the DH consultation on 28th June 2012, Dr. Allan Pacey, Chair of the BFS, said:

   "The British Fertility Society is absolutely committed to upholding the principles enshrined in the Human Fertilisation and Embryology Act. However, in today's difficult economic climate, it is clear that we must take a long hard look at how the fertility sector in the UK is regulated and see whether there are alternative models that can do this more efficiently. Whilst it is under consideration, we currently have no firm view of how this might work, however we will be studying the Government's proposals carefully and will be consulting with our membership over the summer to formulate a response to the consultation. Improvement in the current process of regulation would be supported by the Society, although change for change sake without clear evidence of benefit would not."

Process for Developing this Response

7. The response from BFS members set out in this document has been developed through a process of detailed consultation and discussion with members and stakeholders. Key stages in this process have been:

12th July 2012	Meeting of the BFS Executive Committee
25th July 2012	BFS members invited to submit written comments
30th August 2012	Deadline for responses from BFS members
4th September 2012	Workshop for BFS members held in Newcastle
25th September 2012	Draft response circulated to BFS Executive
27th September 2012	Session at BFS Senior Staff Conference
28th September 2012`	Response submitted to DH