BFS Response to HFEA Consultation on HFEAct revision

The British Fertility Society (BFS) is a professional body for those working in the field of fertility. The current membership is approximately 1100, of which approximately half are doctors working as clinicians in Reproductive Medicine. Other membership categories include Fertility Nurses, Scientists, Fertility Counsellors, Fertility Clinic Managers, paramedical (others health care workers) and Associate (lawyers and others working in related fields).

The BFS has prepared the following responses to the HFEA questionnaire survey on reform of the HFE Act. This document was prepared jointly by the Executive Committee and the Law, Policy and Ethics Special Interest Group of the Society. Members of the Society were surveyed as part of this process.

We have indicated our opinion as requested using the key below, with the BFS choice being highlighted and underlined. We have added a narrative response to all relevant questions, and the response should be considered in its entirety.

This document does not exhaustively cover all aspects of Act reform, and the Society will prepare a further document laying out the views and ideas of its members on these matters. We are committed to engaging effectively with the process of Act reform, in order to protect the interests of our patients and members.

Key
SA = Strongly agree
A= Agree
D=Disagree
SD= Strongly disagree
U = Unsure
NA = Prefer not to answer

Patient safety and promoting good practice

12. *To what extent do you agree or disagree that the HFEA should have greater freedom to vary its inspection regime?*

Response. **SA/**A/D/SD/U/NA

- It is appropriate for the HFEA to have greater flexibility for inspecting clinics that are deemed to be low risk. Such an approach could encourage compliance and thus reduce the burden for clinics.
- Over regulation can have negative effect on care quality by diverting clinic resources to the inspection process rather than patient care.
- A flexible inspection process based on risk is consistent with CQC procedures.

13. *To what extent do you agree or disagree that there should be more flexibility in the appointment of clinic leaders, for example introducing the*

option of a deputy PR, and broadening the criteria for the qualifications and experience required to be a PR?

Response SA/A/D/SD/**U/**NA

- The BFS strongly supports the view that the PR role within the legislation is no longer appropriate for the structure of fertility services and the changes that have occurred in the wider aspects of healthcare regulation and professional practice.
- The BFS is not convinced that a deputy PR is the best option and a more fundamental change should be considered. This should be based on the system of professional accountability that underpins all UK healthcare.
- Individuals are accountable to their professional body with whom they should be registered. Under their quality management systems, clinics will have a structure for accountability within their professional groups.
- In healthcare systems, the roles of management and professional accountability are separate and potentially conflicting. This needs to be considered in relation to the PR role. The role of clinic leader and PR are not necessarily aligned.
- There are different models that can be considered that are now more appropriate for modern healthcare. An example is that required for CQC registration[1]. The BFS looks forward to discussing with the HFEA alternative options that are more appropriate to current clinic structure and professional practice.

14. *To what extent do you agree or disagree that the HFEA should have a broader, more effective range of powers to tackle non-compliance?*

Response. SA/A/**D**/SD/U/NA

- If there were significant concern about patient safety related to a non-compliance, the BFS would support appropriate, effective sanction. No evidence is presented that the current powers are ineffective in ensuring patient safety.
- The HFEA already have a broad range of powers available to them including referral for criminal prosecution, making Directions, preparing and requiring compliance with the Code of Practice, licence variation, and licence withdrawal. The Inspection Reports for each clinic are graded on the HFEA website thus making the public aware of the clinic's performance.
- There are clear distinctions between the consequences of non-compliance e.g. the late submission of data has no direct implication for patient safety, or an error in laboratory management that results in embryo misidentification. The powers of the HFEA should be proportionate. Unless the powers are comparable to sanctions applied by similar regulators, they are likely to be challenged legally and thus be more problematic than helpful.

15. *To what extent do you agree or disagree that the HFEA should have a broader range of powers to impose financial penalties across the sector?*

[1] https://www.cqc.org.uk/guidance-providers/registration/what-registration.

Response. SA/A/D/SD/**U**/NA

- Whilst the ability to impose fines may be attractive to the regulator, a more critical analysis of the justification, implications and potential consequences is required.
- The judicial sentencing remarks in relation to a CQC case provide a basis for how fines maybe determined.[2] In a case of serious harm to an individual patient or potential harm to many, revocation of a licence might be the safer option. For regulatory breaches, such as late submission of data, a fine appropriate to the patient risk of the non-compliance may not be a deterrent to a private clinic. A large fine may result in legal challenge that would be expensive for the Authority.

16. *To what extent do you agree or disagree that there should be an explicit duty on the HFEA and clinics to act to promote patient care and protection?*

Response. SA/A/D/SD/**U**/NA

- This question requires a longer response to explain that disagreement with the legislative proposal does **not** imply lack of concern about patient care.
- Caring for patients is and must be the fundamental motivation for all those working in the healthcare service. The BFS represents those working in fertility clinics whose prime objective is not only to help patients to safely achieve a successful pregnancy, but to provide support during a potentially difficult and distressing time. Whilst supporting legislation with similar aims, the BFS is also aware that, despite the best intentions, inappropriate regulation can be detrimental to patient care by focussing staff time to regulatory requirements rather than direct patient care.
- The consultation does not explain any associated additional powers that revised legislation would provide for the HFEA. The BFS is unable to support this proposal without understanding the intentions for implementation and regulation.
- There are already professional standards and regulation[3]. The Professional Standards Authority states that "*regulation is simply a way to make sure that healthcare professionals are safe to practise and remain safe to practise throughout their career".* Safety is at the heart of professional regulation. If a professional is thought to be non-compliant with the standard set by their professional body, appropriate sanctions can be taken.
- The original intention of the Act is summarised in its Introduction [4]. The issues pertinent to this original intention remain valid and are supported. To revise the

[2] https://www.judiciary.uk/wp-content/uploads/2022/07/R-v-Dudley-NHS-Trust-sentencing-remarks-191121.pdf.

[3] https://www.professionalstandards.org.uk/news-and-blog/blog/detail/blog/2018/04/10/professional-healthcare-regulation-explained.

[4] "*an Act to make provision in connexion with human embryos and any subsequent development of such embryos; to prohibit certain practices in connexion with embryos and gametes; to establish a Human Fertilisation and Embryology authority; to make provision about the persons who in certain circumstances are*

Act to include an "*overarching focus on patient care"* would require a fundamental change of parliament's intention for this legislation.

- Other legislation (Health and Social Care Act 2008) provides for parliament's intentions in relation to patient care. No case has been made for duplication in the HFEAct.
- There are other regulators e.g. ASA and CMA, that have already proved that they can work with the HFEA. Duplication of their function is not indicated.
- The statement that "*the Act is silent on patient care*" is not justified. The HFEAct, as implemented, already includes patient care. Clinics are required to report adverse events, serious adverse events and serious adverse reactions. The definition of serious events applied in healthcare in the UK is broad[5]. The HFEA sets its criteria for reporting (Directive 0011, licence conditions T118 to T122) that include events related to patient care e.g. OHSS. Non-compliance can result in variation or revocation of a licence.
- "Patient care" is not standard terminology within the documentation of regulation of healthcare provision. In assessing hospital care, the CQC asks if the service is "*safe, effective, caring, responsive to people's needs, and well led".*[6] All these features are currently within the HFEA inspection process.
- NHS England describes personalised care; "*Personalised care means people have choice and control over the way their care is delivered. It is based on what matters to them and their individual strengths and needs."* [7] Regulatory powers that could restrict such choices are not appropriate.
- The HFEA report on the State of the Fertility Sector demonstrates that the risks to patient safety are very low.[8] There were no Grade A serious events reported. Severe OHSS occurred in less than 1% of cycles. The number of complaints received by the HFEA was 76, representing about 0.1% of treatments provided. The Regulators Code states that "Regulators should base their regulatory activities on risk".[9] There is no evidence that the proposed addition to the HFEAct is necessary or will be effective.

17. *To what extent do you agree or disagree that the HFEA should have a broader range of powers to tackle related fertility services not taking place in licensed clinics?*

Response. SA/A/D/**SD**/U/NA

- The problem with this proposal is that the term "fertility services" is not defined.

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to be treated in law as parents of a child; and to amend the surrogacy arrangements Act 1985 https://www.legislation.gov.uk/ukpga/1990/37/introduction.

[5] https://www.england.nhs.uk/wp-content/uploads/2015/04/serious-incidnt-framwrk-upd.pdf.

[6] https://www.cqc.org.uk/care-services/what-expect-good-care-service/what-can-you-expect-good-hospital.

[7] https://www.england.nhs.uk/personalisedcare/what-is-personalised-care/.

[8] https://www.hfea.gov.uk/about-us/publications/research-and-data/state-of-the-fertility-sector-2021-2022/.

[9] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/913510/14-705-regulators-code.pdf.

This is likely to give rise to legal issues. Some examples of current non-licensed "fertility services" that might be included in such a definition are given below.
    - A gynaecologist removes a large polyp in the uterus that is impairing fertility.
    - A urologist repairs a varicocele that may be causing a low sperm count.
    - Clomiphene is given in a general gynaecology clinic to induce ovulation
    - The provision of contraception, sterilisation, reversal of sterilisation and abortion are all related to fertility so it could be argued that these would be included under this broad definition.
- Fertility services that do not include licensed treatment must be registered with the CQC. Moving these other services to HFEA regulation cannot be justified, would greatly increase regulation, and require significant expansion of the HFEA.
- There are some Complementary and Alternative Medicine (CAM) clinics [10] that provide fertility services. The CAM sector works alongside, although mainly outside, NHS services. The BFS is aware of and supports the HFEA concerns about some aspects of this where it affects fertility patients. It is more appropriate that problems in the CAM sector are addressed generally and not specifically in relation to fertility.
- Many clinics provide services that are regulated by the CQC alongside the service that is regulated by the HFEA. Whilst there is a working relationship between the HFEA and the CQC, there is a risk of duplication and potential conflict in requirements. The original legislation related to the creation, use, storage and research on embryos and gametes. It also provided protection for gamete donors and their recipients. Extension of the regulatory role of the HFEA into the broader field of healthcare provision is not justified and not consistent with the government's intention to reduce the regulatory burden.

18. *To what extent do you agree or disagree that the current appeals process should be changed?*

Response. **SA**/A/D/SD/U/NA

- The appeal process is, and must be, set in legislation. It is not appropriate that the HFEA be responsible for deciding the appeals process against their own decisions. The Appeal process must remain independent of the HFEA.
- Nonetheless, it is clear that implementation of the current legislation is unnecessarily difficult to implement both for the HFEA and the appellant. The legislation should be revised to take account of the interests of all the parties including the costs.

19. *To what extent do you agree or disagree that there should be more flexibility for the HFEA to make rules governing the setting of standard licence conditions?*

[10] https://www.nhs.uk/conditions/complementary-and-alternative-medicine/

Response. SA/A/D/SD/**U**/NA

- Details of the flexibility requested by the HFEA are not given so the BFS cannot give a definitive answer to this question. The rules for challenging HFEA decisions should be in legislation and must be appropriate to the risk .
- This issue is **not** about patient safety. If an agile response is required related to an individual clinic, this could be managed by variation or revocation of a licence.
- Since standard conditions apply to all clinics, it is essential that those who are providing and receiving fertility services have the right to participate in and, if necessary, challenge decisions that may determine professional practice. If clinics have restricted ability to question licence conditions, this would be inconsistent with a regulatory structure in which the regulator should engage with patients, fertility service providers and relevant professionals to provide better patient care.[11]
- It is not clear whether the current process for changing standard conditions is a problem related to the legislation or its implementation. If it is a problem with the legislation, then this should be corrected by Parliament. If the problem is with its implementation, this could be improved without legislative change.

20. *If you would like to comment further on issues related to patient protection and how the HFEA regulates, please tell us more.*

Access to donor information

21. *To what extent do you agree or disagree that clinics should be required by law to inform donors and recipients of potential donor identification through DNA testing websites?*

Response. SA/A/D/**SD**/U/NA

- The BFS would support the specific inclusion of information relating to DNA websites in the Licence Conditions but not in legislation.
- Good practice must ensure that this information is given to donors and recipients. This already happens. The main concern relates to previous donors and recipients for whom this is an unanticipated potential problem. Prescribing the provision of information such as this in legislation is not necessary, and potentially harmful as it lacks flexibility to reflect future developments, of which the growth in DNA testing websites (direct to consumer genetic testing services) are an example.

11 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/913510/14-705-regulators-code.pdf.

- Licence conditions T58 and T59 list the information that must be given to gamete donors.[12]
- The BFS recognises the ethical challenges particularly in relation to commercial genetic testing and kinship identification. Given the topical and rapidly developing field, it is not wise to make changes in legislation in haste.

22. *To what extent do you agree or disagree that the Act should be amended to provide parental and donor choice to opt for anonymity until age 18 or identifiable information after the birth of a child?*

Response. SA/A/D/SD/**U**/NA

- Known donation is already possible under legislation and this is currently happening via mutual agreement with donors e.g. by finding donors/recipients online who wish to be contactable/in a relationship at the point of treatment[13] . Identifying information that the clinic can provide under these circumstances, is dependent on donor consent and does not need legislative change.
- Active recruitment by clinics of donors who agree to be identifiable to the parents or younger donor conceived children is ethically and socially challenging. The BFS welcomes further debate but recognises that it does not need legislative change.
- The use of DNA testing websites to find donor connections before the donor conceived person turns 18 conflicts with the intentions of the legislation and the underlying ethical deliberations. [14] [15] The ethical debate is essential but is not part of this consultation.
- Notwithstanding the comments above, it would be prudent to provide future proofing options in legislation where needed. For example, the HFEA cannot disclose identifying information from their Register until the donor conceived child is 18. Legislation does not provide an option of disclosing information to the parent. Any change in legislation related to disclosure from the Register must include appropriate requirements for the process of disclosure by the Authority, taking account of the welfare of donor, recipients and the child.

[12] https://portal.hfea.gov.uk/media/ihkjnfqq/2022-07-01-code-of-practice-2021.pdf. Guidance note 4.
[13] Michiel De Proost, Nicky Hudson & Veerle Provoost (2021) 'Nothing will stop me from giving the gift of life': a qualitative analysis of egg donor forum posts, Culture, Health & Sexuality, 23:5, 690-704, DOI: 10.1080/13691058.2020.1722242

[14] L Frith, O-060 Ethical implications of the direct to consumer genetic testing. What should donors and recipients know?, *Human Reproduction*, Volume 36, Issue Supplement_1, July 2021, deab127.040, https://doi.org/10.1093/humrep/deab127.040
[15] L Frith, L Gilman, C Redhead, M Fox, N Hudson, F MacCallum, J Kirkham Brown, O-219 Donor conception and Commercial Genomics: how are donor conceived people, their parents and donors using direct-to-consumer genetic testing?, *Human Reproduction*, Volume 37, Issue Supplement_1, July 2022, deac105.138, https://doi.org/10.1093/humrep/deac105.138

23. *To what extent do you agree or disagree that the Act should require all donors and recipients to have implications counselling before starting treatment?*

Response. SA/A/D/SD/**U**/NA

- This question conflates information giving and counselling which we know is also a long-standing problem highlighted by donors and patients i.e. people complain about or are confused as to whether they have or have not received 'counselling'[16] . This reflects a similar confusion amongst regulators and service providers.
- It is illegal to carry out any medical treatment without consent. Valid consent requires discussion and the provision of information (oral and written) about the procedure to be carried out, the risks and potential outcome, and the implications of treatment. The person taking consent must be appropriately trained and competent to take valid consent.[17] Written consent should record that specific information has been given.
- By contrast, counselling is a voluntary engagement between participants and counsellors.[18] The provision of a counselling session should be documented but the discussion is confidential. Such therapy is provided by those with professional qualifications and the required knowledge of infertility and related treatments.
- In practice, the distinction is blurred. If the HFEA has grounds to believe that the professional requirements for taking valid consent are not fulfilled or that there has not been an offer of independent counselling, they have powers within their licensing structure to take appropriate actions.
- The BFS understands the ongoing conflict related to the definition and provision of implications counselling. This issue needs further discussion but is more likely to be aggravated by legislation than resolved.

24. *If you would like to comment further on issues related to access to donor information, please tell us more.*

Consent

25. *To what extent do you agree or disagree that the current consent regime could be simplified (for example to an 'opt out' model) in ways that continue to provide protection to patients?*

Response. SA/A/D/SD/**U**/NA

[16] Loyal, S., Hudson, N., Culley, L., & Weis, C. (2023). The experience of counselling for UK egg providers. *Counselling and Psychotherapy Research*, 00, 1– 7. https://doi.org/10.1002/capr.12613
[17] https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/decision-making-and-consent https://www.nhs.uk/conditions/consent-to-treatment/
[18] https://www.nhs.uk/mental-health/talking-therapies-medicine-treatments/talking-therapies-and-counselling/counselling/.

- Although not specified in the question, it is assumed to be related to problems of legal parenthood. This response is drafted accordingly.
- There is strong agreement that the consent process needs to be simplified. This must be a major focus of any revision of the Act.
- The problems that have resulted in legal challenge are infrequent but high profile and costly. The conflicts have mainly arisen from problems with completion of the Legal Parenthood forms. Such problems have occurred in many clinics including those with otherwise excellent compliance history. It is appropriate therefore to seriously consider that the underlying problem may be with the legislation and its implementation rather than patient/clinic compliance.
- The BFS considers that an opt-out option is unlikely to be responsive to all the variables seen in clinical practice.
- The BFS is developing alternative legislative options in relation to legal parenthood and posthumous use and looks forward to discussing this constructively with the HFEA.

26. *To what extent do you agree or disagree that the sharing of fertility patient data in a non-fertility medical setting should be brought in line with the current regulations for the sharing of other patient/medical data between healthcare providers?*

Response. **SA**/A/D/SD/U/NA

- The BFS agrees that the legislation is unnecessarily restrictive in relation to the sharing of medical information where it is in the interest of the patient.
- The HFEAct does not restrict the transfer of information from a non-licensed medical setting to the fertility clinic. The legal restrictions relate to transfer of information from the fertility clinic to the non-licensed medical setting[19]. The written consent that is required to overcome the resulting problems is an unnecessary burden for patients. Legislation should be amended such that the sharing of medical data about fertility treatment is consistent with general healthcare provision in the UK.[20]
- The HFEAct includes data disclosure restrictions on staff in the HFEA who have access to data on their Register. Some of these should be retained.

27. *To what extent do you agree or disagree that consent for donating embryos should be extended to allow patients who wish to, to give consent to research embryo banking?*

Response. **SA**/A/D/SD/U/NA

[19] https://www.legislation.gov.uk/ukpga/1990/37/section/33A.
[20] https://www.england.nhs.uk/wp-content/uploads/2019/10/information-sharing-policy-v4.1.pdf

- The establishment of a central embryo bank for research would be supported. Consideration should be given to achieving that by a change in implementation of the existing legislation.
- The process of taking consent for donation of embryos or gametes to a bank should be consistent with HRA guidance.
- Since the HFEA would still have regulatory powers over the storage of embryos in the bank, the management of the embryo bank must be independent from the HFEA.
- Consideration should be given to allowing patients to opt out of some procedures e.g. studies that involve live animals. Patient views about this should be sought.

28. *Further comments on issues related to consent.*

Scientific developments.

29. *To what extent do you agree that the Act should explicitly give the HFEA greater discretion to support innovation in treatment?*

Response. SA/A/D/SD/**U**/NA

- The BFS believes that it is not the role of a regulator to support innovation, but legislation and its implementation should facilitate and not inhibit innovation.
- The HFEA have stated that they have adequately fulfilled government requirements related to innovation.[21] Nonetheless, the HFEAct currently places restrictions on innovation. These barriers need to be addressed.
- In relation to a Treatment Licence, the HFEAct states that HFEA cannot authorise any activity unless it appears to be "necessary or desirable" [22]. This is no longer appropriate where medical practices are evaluated, accredited and monitored by regulatory systems that were not present in 1990. Support for innovation in medical technology and care has many options[23]. Innovative technologies are regulated to confirm safety before accreditation and adoption into clinical practice. Such evaluations are routine via IRAS and by the MHRA. Further regulation by the HFEA is not justified and the "necessary and desirable" requirement should be removed.
- The HFEAct separates Research and Treatment licences and embryos used for research cannot be used in treatment. Thus, there is ambiguity about whether clinical embryology research is allowed under a Treatment licence. This is a barrier to innovation and should be clarified.

[21] http://ifqtesting.blob.core.windows.net/umbraco-website/1351/hfea-innovation-and-regulation-plan-feb-2017.pdf.
[22] https://www.legislation.gov.uk/ukpga/1990/37/schedule/2
[23] https://www.gov.uk/government/publications/uk-life-sciences-support/medical-technology#regulatory-and-health-technology-assessment-development-stage-uk-support-organisations.

- "Sandboxes" are new and have limited application in the medical field.[24] There are well established regulatory procedures for medical research under the HRA process. Additional regulation by the HFEA, which has limited experience in clinical research regulation, is unnecessary duplication that is likely to inhibit innovation.

30. *To what extent do you agree or disagree that changes should be made to the Act to allow Regulations to be made (by secondary legislation or statutory instruments) to enable future amendment and extension?*

Response. **SA**/A/D/SD/U/NA

- This procedure worked well in relation to mitochondrial transfer and is supported. This will future proof the legislation in a rapidly developing scientific medical and social field.
- Many parts of the legislation can, and some have been, amended by Regulations. It is recommended that the HFEAct should be reviewed to ensure that the sections that can be changed by Regulations remain appropriate.

31. *If you would like to comment further on issues related to scientific developments and how the HFEA regulates these, please tell us more.*

General Comment

The BFS notes that several questions relate to a potential increase in the HFEA's remit which would in turn require extra resource. Consideration needs to be given as to how any increase in the HFEA's functions would be funded. If the money required is to be raised via licence fees, then it is likely that this will be passed on to some extent to patients. Similarly increases to the cost of research licences may act as an impediment to research.

[24] https://pubmed.ncbi.nlm.nih.gov/34254275/ https://www.cqc.org.uk/what-we-do/how-we-work-people/evaluation-cqcs-regulatory-sandboxing-pilot.