Consultation on Proposals to Transfer Functions from the Human Fertilisation & Embryology Authority and the Human Tissue Authority

Name of Responder:

PROGAR (Project Group on Assisted Reproduction) was set up originally at the time of the Warnock Inquiry in the 1980s, taking forward work done by a predecessor group which had submitted evidence to that Inquiry on behalf of the British Association of Social Workers. PROGAR continues to be administered by the British Association of Social Workers, the largest professional association for social workers in the UK with more than 14,000 members employed in frontline, management, academic and research positions in all social care settings

PROGAR draws on the knowledge and expertise of social workers in the fields of infertility counselling, donor linking, adoption and fostering, child care, family work and health care as well as that of other groups of professionals, academics and people directly affected by donor conception. We work in partnership with:

- British Association for Adoption and Fostering
- British Infertility Counselling Association
- Cafcass (Child and Family Court Advisory and Support Service)
- DC Network
- NAGALRO (National Association of Guardian *ad litems* and Reporting Officers)
- UK DonorLink
- Individual academics

PROGAR has contributed to policy discussions and policy formation in assisted conception on many occasions. The principles underlying PROGAR's work have always been that those conceived as a result of donor procedures and their families, donors of gametes and embryos and their families, those undergoing fertility investigations and treatment and those involved in surrogacy arrangements should receive the best care possible, including access to professional support. We firmly believe in the importance of early disclosure of origins to donor- conceived individuals and those born as a result of surrogacy arrangements, their right of access to identifying information about their donor(s) or surrogate and that policies and services should take full account of the lifelong implications of donor conception or surrogacy.

CONSULTATION RESPONSE

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.*

We are commenting solely on matters to do with the HFEA; those concerning the HTA fall outside of our area of core interest and expertise, namely the family building and well-being aspects of those directly affected by donor conception: donor conceived people; their families; donors and their families including their non donor-conceived offspring; and the well-being of those affected by surrogacy. While there are similarities with family building using other forms of assisted reproduction, we strongly believe that there are unique aspects where there is third party involvement in family building. Where donor conception is involved, the family that is formed (and the individual offspring) have to manage the implications of genetic difference over their lifetimes, including the potential and as yet unknown implications of donor mitochondrial use, not only over their own lifetimes, but also for their own descendants.

We are not opposed to the transfer of functions relating to research to the HRA (and see our response at Q2).

We are not opposed to the transfer of <u>regulatory</u> functions per se to the CQC (subject to it being delivered through a specialist arm as indicated in your consultation document as a possibility) but have grave concerns about the transfer to the CQC of those HFEA functions to do with:

(i) maintaining donor conception related information for the central Register and Donor Sibling Link
(ii) policy development and evaluation matters

There are a number of reasons for our opposition to the transfer to the CQC of (i) and (ii) and these are as follows:

- CQC is a regulatory body and hence has no skill or experience in dealing with the release of information from the Register to those seeking information from it because of being directly affected. This work would sit much better with or in an organisation that has skill and expertise in **the release of** personal information and associated intermediary work between those seeking personal information and those about whom personal information is sought.
- CQC is a regulatory body and hence has no skill or experience in policy development and associated consultation with the general public or with professional and personal stakeholders. This work would sit much better with or in an organisation that has skill and expertise in such work.
- We are aware that the Government will seek to extend the powers of the CQC to cover all 4 nations of the UK. This will bring new demands for the CQC at an organisational level as it seeks for the first time to manage the

necessary liaison with service providers, policy makers and so on in all 4 nations and to acquaint itself to an appropriate level with the relevant new systems, procedures and statutes. Demanding though this will be, it will at least be extending its remit within its core business (presuming those currently employed in this role by the HFEA will be transferred into the CQC, bringing their existing knowledge with them). Asking it to take on wholly new functions would, in our view, not be workable.

We make suggestions in our response at Q4 as to where these functions might be better placed.

With regard to inspection and regulation per se, we strongly believe that donor conception treatment services should continue to be regulated and inspected and welcome recognition of that by the Government, acknowledging the importance of ensuring minimum standards in this area of family building through the use of outside assistance. If this work were to be transferred to the CQC then it would need to:

- be carried out through a specialist arm that is well informed about family building and about lifelong donor conception matters
- have a title that reflects its work rather than using the CQC generic 'brand'
- take full account of the information arising from the work of our proposed national information release and intermediary service (see below) as well as that from medical and scientific services and research
- develop close and effective liaison with associated relevant services.

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

We understand that this question is asking for views about the impacts that we could perceive from transferring all HFEA functions except research to the CQC.

In relation to regulation and inspection, we believe that there could be some advantages to service providers. Existing overlaps between current non-HFEA inspection regimes involved in inspecting non-HFEA licensed aspects of service provision and that of the HFEA have arguably an improved likelihood of being removed through the transfer (we are aware that some work is also ongoing currently between the HFEA and CQC on this). However there would almost inevitably be hiccups in any transition period, perhaps especially in those parts of the UK where the CQC does not operate currently. Additionally we base our comments on the assumption that there would be a transfer of some of the HFEA staff to the CQC into a specialist arm.

We also believe that many patients and donors value the fact that services are licensed and inspected. It will therefore be important that this retains a high profile, including a name that reflects its work, as stated above.

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

This does not fall within our area of knowledge or expertise as this proposal relates to the current HFEA functions in relation to research licences for medical and scientific research only.

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?*

Given PROGAR's interests and expertise in child and family welfare matters (including those relating to information release and intermediary services) in relation to donor conception, surrogacy and adoption, our response deals solely with HFEA matters associated with donor conception and surrogacy, not the HTA. We use a lifespan and family building perspective to do so.

Our belief is that there are core functions (in addition to inspection and regulation) that need to be delivered safely and ethically, putting the needs of those directly affected at the centre. These are:

1. The accurate and appropriate collection of full information, including biographical information, by services that recruit gamete(s) donors and/or provide donor conception treatments (including where surrogacy is involved and potentially donated mitochondria).
2. The timely and safe transfer of such information, fully validated, onto what is currently called the HFEA Register of Information no later than at the birth of a donor-conceived child.
3. The safe and accurate updates to such information as and when it becomes available.
4. The safe and accurate recording of information, including updates, onto what is currently called Donor Sibling Link.
5. The release of information and provision of professional support and intermediary services as necessary to those seeking information and/or contact with those genetically related through donor conception.
6. The review and/or development of policy with regard to donor conception matters that attends to medical and scientific matters *within* a family building model in recognition that the core purpose of the use of donor conception treatments is to bring about a family. Putting long term child and family welfare at the core of all policy and service developments is crucial.
7. The regular review of evidence from psycho-social practice, research and theory and from user feedback (including from those throughout the life cycle not simply from patients and donors at around the time of treatment/donation). Such evidence to include that from related fields of child and family welfare.

The underlying principles as enacted in the 1990 and 2008 Acts lead us to conclude that policies and services to do with donor conception should be developed and delivered to a standard that meets the desired outcomes of:

(i) enabling parents to raise their children with openness from an early age about their donor conception and in a happy, healthy and supportive environment;

(ii) enabling those seeking information about and/or contact with those genetically related through donor conception to have confidence that it is robust and respectful in terms of accuracy and sufficiency and to receive appropriate levels of professional support in doing so in recognition of the potential complexity of the lifelong implications of third party conception.

It is our view that such standards have not been met adequately to date by the HFEA or the fertility treatment sector generally.

PROGAR has maintained a regular informal dialogue with the HFEA since the HFEA's establishment in 1991. Until recently, HFEA staff attended PROGAR's meetings as observers (although this presence was withdrawn as part of the HFEA's review and implementation of their professional stakeholder engagement policy). PROGAR has also held formal meetings with HFEA staff over many years: initially this was in conjunction with the British Infertility Counselling Association and, more recently, as part of the Professional Stakeholders Group. Some of our members have in their individual capacities acted as Inspectors, External Advisers and as an HFEA Member. PROGAR has also regularly responded to HFEA consultations. It is therefore with considerable depth of knowledge and experience that we make our comments.

Our experience is that the HFEA has traditionally worked hard to improve its inspection regime through seeking feedback and keeping abreast of broader developments in the field of regulation. Sadly, its record in relation to the inspection of counselling services is poor, despite this being raised with it on many occasions by PROGAR and BICA. The HFEA has also traditionally sought to have regular contact with professional stakeholders and with patients. At times, it has approached consultations and policy development creatively and openly. However our experience is that, especially in recent years in relation to third party conception family building, the HFEA culture has become increasingly defensive, risk averse and adversarial. It appears to struggle with engagement with stakeholders and other interested parties in a 'listening' way and instead is more likely to use such contacts in 'top-down' fashion to cascade information that they wish to impart. Most importantly in our view is that recent years have seen far too little progress towards putting the family that is formed at the core of its thinking and the HFEA's approach to information release from the Registers falls far short of what is acceptable good practice. This has contributed to its highly selective use of research, theory and practice evidence from both the field of donor conception and the broader fields of child and family welfare in its decision-making.

Recent examples to illustrate our concerns about policy development are the conduct of the recent Donation Review, the associated HFEA decisions in relation to payment to donors for which no support from the research evidence can be found, see for example ESHRA 2012[1]) in particular and the subsequent appointment of a National Donation Strategy Group where the focus is firmly on improving donor recruitment (incidentally not, in our view, the job of a regulator). In addition we have grave concerns about the HFEA's failure to date – more than 20 years since its launch - to develop and implement policies to ensure that all clinics collect good quality biographical information on donors.

In relation to the release of information from the Register and from Donor Sibling Link, PROGAR believes that the HFEA is not meeting its own policy as agreed at the Authority meeting on 20th January 2009 in response to the report from the multi-disciplinary Steering Group chaired by the British Infertility Counselling Association (BICA) and funded by the Department of Health (DH), the Scottish Executive and the Bruce Trust (BICA, 2003[2]) to look at the needs of those applying for information from the Register. In particular we believe that it is not meeting the following decisions that it made:

- The HFEA should ensure that donor-conceived people receive information on counselling before they make an application to the HFEA. This information should include *adequate* signposting to counselling services. Once an application has been lodged, the applicant must be told that they are free to change their mind at any point before the information is released.
- Currently there are a limited amount of people with the specialist counselling skills to address the emerging needs of donor-conceived people. *The HFEA has a role in engaging with the sector to ensure there is adequate provision of appropriate counselling expertise available to donor-conceived applicants*.
- *Front-line Register staff should have adequate training and skills to enable them to deal sensitively with applicants.*
  (our italics)
  HFEA Minutes, item 10 [HFEA (21/01/09) 485]
  http://www.hfea.gov.uk/docs/2009-01-21_Authority_Meeting_minutes.pdf[3]

Currently, the HFEA only provides details of a generic counselling database (British Association for Counselling and Psychotherapy) and the British Infertility Counselling

[1] http://humrep.oxfordjournals.org/content/27/suppl_2.toc?etoc

[2] BICA (2003) 'Opening the Record - Planning the provision of Counselling to People applying for information from the HFEA Register – Report of the HFEA Register Counselling Project Steering Group' BICA Publications available at: http://www.bica.net/downloadable/opening-record

[3] The paper that was taken to the Authority at this meeting can be found as follows: HFEA (2008) 'Opening the Register – a principled approach' TRIM reference 2008/07083 http://www.hfea.gov.uk/docs/AM_Item_9_Jan09.pdf *accessed 29.8.2012*

Association and advises enquirers that they can seek referral to GP counsellors. This does not, in our view, fulfil its role in 'engaging with the sector to ensure adequate provision of *appropriate* counselling expertise to donor conceived registrants' in respect of information release. It also provides details of the Donor Conception Network (the peer support group, primarily for families) and UK DonorLink (the voluntary register service for those conceived prior to the implementation of the 1990 Act) and website information about the implications of seeking information from the Registers. It does not make any provision either for those who wish to avail themselves of a counselling or intermediary service specialising in this work for those affected by donor conception or for those unable to afford private counselling or intermediary services. The HFEA has enabled a small number of its front line staff who deal with Register enquiries as a part of their core post to receive basic counselling skills training[4] but we have been unable to establish whether this is now part of their role specification, whether they receive supervision from a qualified counselling supervisor, or whether there is any ongoing user evaluation of the quality of their service.

<u>We believe that functions (1) to (4) should be met as follows:</u>

- The collection of the data on donors, treatment with donor gametes and live birth outcomes should continue to be a statutory obligation. These should be held on a single dedicated Donor Conception Register run by a body competent in handling large data sets and able to do so for the whole of the UK. Such a body should also maintain Donor Sibling Link. National minimum standards for clinics and the Registers should be in place to ensure the quality, safety and sufficiency of the information collected, including:

    - A (newly developed) Donor Information form that includes a *requirement* for biographical information. The categories for information collection should be kept under review in the light of emerging research and practice evidence and user feedback.

    - Donor gamete(s) to be released for use only after donor information is provided in full.

    - Clinics to be responsible for preparing a 'child's file' comprising the Donor Information form(s), details of treatment cycle and legal parentage to be passed to the central Register following the notification of the child's birth and validated at that stage. Clinics to retain a copy for their own records but all requests for information from those affected to be dealt with centrally.

    - Robust systems for collecting and updating information from the parties concerned (including family members in the case of mental incapacity or

[4] Progar would like to point out an apparent inaccuracy in the DH Consultation document at paragraph 132 page 61. Our understanding from the HFEA is that its staff have undergone counselling *skills* training but not counselling training – there is an important difference. We further understand that *one* of the staff has completed a Diploma in Counselling because of personal interest but we understand she is not a practising counsellor.

death) and supplying updated information to existing enquirers where appropriate.

- Central Register services to be responsible for updating such files to include non identifying information about any other children conceived using the same donor(s) and any other new information as it becomes available.
- Central Register services to be responsible for releasing information as required to a national information release and intermediary service (see below)

<u>We believe that function (5) should be met as follows:</u>

- There should be a centrally funded dedicated UK wide information release and intermediary service through which all enquiries to the Register and Donor Sibling Link are routed. Given that numbers seeking information are, as yet, quite low (though rising), that professional expertise in DC information release and intermediary services is currently held predominantly by the voluntary register, UK DonorLink, for those affected pre August 1991, and that the 2008 Act allows for the HFEA (and hence presumably its equivalent) to take power of authority to run a voluntary register (Section 31ZF) the national service should include those affected pre and post August 1991.

  In addition, we have grave concerns about the position of those born through surrogacy arrangements (not currently a statutory responsibility of the HFEA unless the surrogacy involved donated gametes) and seeking information from the Parental Order Register at the age of majority. There are currently no plans to provide services to this group of people and we believe this to be wrong. Their needs could therefore be met through the proposed UK information release and intermediary service.

  Consideration should be given to the UK service employing staff (appropriately qualified and with specific additional training to manage the unique features of donor conception) based in post adoption support services with a small number of centrally based staff to support them, thus enabling the exchange of experiences across services with shared interests as well as being potentially cost effective. Such services should be subject to a regulation system that applies across the UK, perhaps through the Ofsted system that currently inspects English post adoption services.

  National minimum standards should be in place to ensure its quality, safety and sufficiency, including:
  - A ‘triage’ system that assesses the support needs of those seeking information.

- Staffing requirements that reflect the need for professional qualifications and experience in sensitive areas of information release and intermediary work.

<u>We believe that functions (6) and (7) should be met as follows:</u>

Should the HFEA be abolished, the setting of the national minimum standards and development of policy in relation to donor conception should be undertaken by the relevant government department, currently the Department of Health for the 4 nations, with the support of advisers seconded for the purpose and chosen for their knowledge and experience in sensitive matters of information collection and release, intermediary work and family work. Given *current* legislative requirements under the HFE Act 1990, the body that is currently constituted as the HFEA could become an Expert Advisory Board to the government department. Such a Board must, in our view, have members selected for their expertise in child and family policy and practice and members with direct experience of donor conception, including donor offspring, together with a smaller number of those with appropriate medical, scientific and other experience.

As a reflection of the core purpose of donor conception treatment as family building, close collaboration with those government departments across the UK concerned with family policy, currently for example primarily the Department for Education for England, should be a requirement.

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

Our view is that, should the HFEA be retained, there is a need for significant improvements to its practice. The Authority membership is, we believe, too large. Its work is also adversely affected by the lack of representation to date from those directly affected, in particular donor conceived adults; this runs counter to government policy elsewhere that states the need to put those directly affected at the centre of policy and practice developments. In addition, the membership has to date been dominated by medical, scientific and ethical professional interests and has not adequately represented those with psycho-social interests in family building using third party assistance.

The HFEA's history of being an effective regulator has also been a checkered one. We are not qualified to comment on its robustness in relation to medical and scientific matters but its attention to the inspection of counselling and donor conception services, donor conception services is poor. In addition we believe that the HFEA has been too cautious in its interpretation of its responsibilities with regard to the inspection of satellite units and of links between UK clinics and those overseas. In similar vein, there appears to be a growing underground 'market' for the buying of gamete(s) and a growing use of surrogacy arrangements and we are not confident that the HFEA is sufficiently proactive in trying to keep one step ahead of such developments rather than being merely reactive.

These comments are in addition to those responses supplied above.

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.*

These are difficult questions for bodies such as ours to answer. We are professionals offering our considered views as to the best way to deliver good quality services that are 'fit for purpose' and hence are not focussed on the relative costs of services – neither is this within our sphere of expertise. However we would point out that we believe that savings can be made in the longer term when treatment services pay proactive attention in these early stages to the lifelong implications of donor conception or surrogacy.

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?*

Whatever the outcome with regard to the HFEA, we strongly believe there is a need for:

(i) A dedicated Donor Conception Register

(ii) A national service to provide a professionally led UK wide information release and intermediary services to those approaching the HFEA Register, Donor Sibling Link, the pre 1991 Voluntary register and the Parental Order Register.

See our detailed response at Q4 above

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?*

We have serious concerns about the paucity of information in relation to costings of the different options. Although this is not our area of expertise, there is little to indicate any realistic costs associated with the actual transfer of functions and personnel and establishment of new services (which can prove very costly); the costs associated with new liaison responsibilities for both the new service(s) and the services to whom it/they will be required to relate and so on. Without such information, the request for comments on proposed efficiencies is meaningless.

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.*

In addition to the Recommendations made earlier, we also believe that the following should be in place to inform the development and regulation of treatment services and information release and support services:

In relation to donors and surrogates

1. Counselling should be mandatory for donors and surrogates (with a minimum of two sessions available) in order to provide for informed consent to be assured through the time for reflection between sessions, if required.

2. Where the donor or surrogate has a partner, s/he should not be accepted as a donor without their consent.

3. Guidance should be made available to clinic staff and to donors on the importance of providing good biographical information and how to go about doing so.

4. Professional support should be available to prospective and past donors, surrogates and their families in relation to disclosing the donor's (or surrogate's) role in donation/surrogacy and in relation to any difficulties that they face from the impact of donor conception and/or surrogacy.

In relation to recipient parents

1. Counselling should be mandatory for all who wish to undergo treatment using donated gametes/embryos and/or surrogacy (with a minimum of two sessions available) in order to provide for informed consent to be assured through having time for reflection between sessions.

2. The current requirements for parents to agree 'consent to disclosure' should be removed, bringing this area of medical intervention into line with good healthcare practice insofar as treating specialists inform patients' family doctor (and others as relevant, for example, ante-natal services) of the facts of their treatment and outcomes.

3. Recipient parents should be involved in donor (or surrogacy) selection and provided with relevant non-identifying information both at this stage and once a child is born to promote a beginning relationship with the donor (or surrogate) and her/his background to aid them in their parenting role.

4. Professional support in conjunction with peer support from DC Network (where appropriate) should be available to existing parents of donor conceived offspring for their ongoing task of talking with child(ren) of all ages about donor conception and in relation to any difficulties that they face from the impact of donor conception. The same should be available for those using surrogacy.

In relation to donor conceived people

1. Professional support should be available to donor conceived people and their families when seeking information about their origins and when seeking contact with the other party(parties).

2. Professional support, in conjunction with peer support (where appropriate) should be available to donor conceived people in relation to any difficulties that they face from the impact of donor conception. Such support should also be available to assist them in talking with their own child(ren) (if they have any) about donor conception.

In relation to those born through surrogacy arrangements

1. Professional support should be available to those born through surrogacy and their families when seeking information about their origins and when seeking contact with the other party(parties).

2. Professional support, in conjunction with peer support (where appropriate) should be available to those born through surrogacy and their families and to surrogates and their families in relation to any difficulties that they face from the impact of surrogacy. Such support should also be available to assist them in talking with their child(ren) about surrogacy.

In addition:

1. *Birth registration review* - In the adoption context, adopted children are issued with a new birth certificate and this together with their original birth certificate is held by the Registrars General of the 4 nations. A similar system applies where children are born following surrogacy arrangements and commissioning parents are granted a Parental Order. We would like to see detailed consideration of donor-conceived people having their details recorded by the Registrars General in such a way that enables them too to retrieve details of their biological parents at the age of majority. This in turn will enable them to learn (as do adopted people) that other records are held on them elsewhere which might contain information of value to them. In addition changes are required to the birth registration/Parental Order process for those conceived through surrogacy arrangements. At present those applying for their original birth certificate have no way of knowing whether donor gamete(s) were used in their conception and hence that there may be additional information available to them on the HFEA Register. This needs addressing.

2. *Voluntary register for DC post 1991* Evidence from the US-based Donor Sibling Register and developments in Australia and New Zealand suggest that there is a need for a voluntary register open to donors and parents of donor conceived minors who wish to exchange information and/or make contact while the child is growing up (including between families with children who share a donor). There are informal moves in the UK to develop such services on a 'do it yourself' basis. We would like to see this option being explored for the UK along similar lines to those currently eligible through statute to apply for information release.

3. *Opening registers to donors' 'own' children* - Some of the voluntary registers around the world, and that based in the UK (UK DonorLink) are open to non-donor-conceived offspring of donors to register. We would like to see such developments happening for those affected post 1991; we can see no logical reason to exclude them from being able voluntarily to seek information about and/or contact with their half-siblings.

4. *Register for those affected by surrogacy* – there is an urgent need for a debate about register services for those affected by surrogacy, including whether to include them in the donor conception registers, regardless of whether donated gamete(s) have been involved. The issues relating to the UK consequences of surrogacy overseas, must also be addressed.

5. *Preparation for parenthood sessions* - DC Network has been running some very successful Preparation for Parenthood workshops since 2008. We would like to see further work done to develop such workshops to be run around the country and to be made available to all those considering DC treatment.

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

We welcomed the opportunity to take part on the workshop organised by yourselves on 19th September. These are complex matters to consider and opportunities for cross fertilisation of ideas are important. It would have been helpful if such initiatives could also have been extended to members of the public across the 4 nations.

Matters to do with donor conception, surrogacy and assisted reproduction are of major importance. Although they clearly can involve highly technical procedures during the fertility 'treatment' stages, those affected will only be well served if all involved at each stage recognise their lifelong implications see it as a family-building matter rather than a treatment choice **and** put the welfare of those affected - especially the child/adult that is conceived – centre stage.

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

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

We found the Equality Analysis to be rather bland and repetitive. Such documents have become a requirement in many settings but we have rarely been convinced of their usefulness in attending to equality and diversity matters in any meaningful way and that is the case here too.

NOTE: WE HAVE NOT SUPPLIED A COMPREHENSIVE LIST OF THE UNDERPINNING EVIDENCE FOR OUR RESPONSE, ONLY THOSE THAT ARE CITED SPECIFICALLY BUT ONE IS AVAILABLE ON REQUEST.