

SUMMARY OF RESPONSES TO A CONSULTATION ON THE MODERNISATION OF REGULATION AND NEW FEE STRATEGY

Number and source of responses

The HFEA received 56 written responses to the document HFEA consultation on the modernisation of regulation and new fee strategy. Some of these were 'collective responses'. Notably the response from the British Fertility Society (BFS) said it had been circulated to and had the support of all Persons Responsible for licensed units. Also, a joint response was received from Acebabes, CHILD, the DC Network and Issue (referred to as the Patients' Groups response). In addition CHILD forwarded 14 comments from its members.

Breakdown of responses

Professional bodies related to assisted conception	8
Persons responsible/clinic representatives	16
Other professional bodies	7
Other health care professionals	19
Individuals	6 (+ 14 from CHILD)

A list of respondents is included at Annex 1.

Timing of the consultation

The consultation document and summary was posted on the HFEA website and printed copies were widely circulated to individuals and organisations with an interest in reproductive health, health service regulation and funding. These included, but were not limited to, Persons Responsible and Nominal Licensees of clinics, the relevant Royal Colleges, women's organisations, Primary Care Trusts, and Strategic Health Authorities.

Concern was expressed by a number of respondents that the period of time for the consultation was unreasonably short (6 weeks) particularly as it fell within the summer holiday period. It was noted that this contravened Cabinet Office Guidance which states that: 'Twelve weeks should be the standard minimum period for consultation'. In this case, the time of the consultation period was constrained by factors outside the control of the HFEA, specifically the need to prepare a budget in time for Treasury approval. The HFEA had acknowledged this deficiency in process at the onset of the consultation exercise and had sought to complement the written consultation with other processes to ensure stakeholders had the maximum opportunity to contribute their views. These included a series of stakeholder 'hearings' before a panel independent of the HFEA. The panel is to produce a report of recommendations to be considered alongside this summary of responses to the consultation document.

OVERVIEW

A number of common observations were made by those involved in the provision of services related to infertility:

Source of HFEA income

Several responses took issue with the principle adopted by Treasury stated in the consultation document: that the costs of regulation must be met by those being regulated.

One response pointed out that another NDPB, the Food Standards Agency, *'is funded entirely from the public purse, not by regulatory fees on the food industry'*. The BFS accepted the principle, but offered examples of health regulation for which no fee is charged: CHI inspections, regulation of termination of pregnancy services, Hospital Training Recognition Visits.

Magnitude of HFEA funding

Although the BFS, RCOG and Patients' Groups felt that the HFEA had not justified sufficiently the need for significantly increased funding. Other respondents felt able to support this on the basis of the facts as they were outlined in the consultation document.

The fpa (formerly the Family Planning Association) said:

'fpa welcomes the move by the HFEA to examine its current and anticipated workload and prepare to put in place adequate funding arrangements. We would agree that, since its establishment, the workload of the HFEA has increased significantly as a result of factors outlined in the consultation document. It is also beyond dispute that a combination of new developments outlined in the document, as well as unforeseen developments in technology will contribute to continual growth of the HFEA's workload in future.'

A Chief Executive of a major cancer charity said:

'It is my view that the HFEA has a good reputation and is widely thought to be an authoritative organisation in the field of infertility regulation. It is imperative that the HFEA maintains its reputation by developing as an organisation and ensuring that it remains able to better support patients, public and professionals.'

A Chief Executive of a health care provider said:

'My understanding of the budget for the authority is that it has been based on an historical model. In order to fulfil the responsibilities that are now expected, in such a high profile area of public interest, it is essential to bring the resourcing process up to date. This will enable the authority to properly focus on effective regulation rather than on economic survival. This, in turn, would also benefit providers and ultimately patients.'

What clinic fees should cover

Not all of the HFEA's functions are regulatory, and many respondents said that those functions not directly related to inspection and regulation should be funded from the public purse. Areas that should not be funded from fees paid by clinics were identified as:

- Policy
- Advice to government
- Maintenance of the data register funded (RCOG, BFS, Child)
- Research (e.g. stem cell research),
- Legal costs e.g. PGD judicial reviews)

These were identified as areas that should be funded from Government.

There were different opinions on who should pay for information provision. The BFS stated that provision of information should not be funded by licence fees. However, one clinic

clearly understood that HFEA information could support service delivery. *'We would welcome HFEA patient information to replace clinic's own information, as every year we seem to need to provide more detail. This would standardise the information across the UK.'*

The future of regulation

The RCOG noted that: *'many of the regulatory functions of the HFEA could be considerably rationalised'*. However, other responses stress the need for confidence in a regulator.

The National Council of Women said: *'[A] more robust and transparent regulatory framework is necessary but must be seen to be effective...Licensing, monitoring and inspection are worthless if they do not protect the patients. Improved data collection, publication of success rates and current research would enable stakeholders to have a clearer understanding.'* A health charity chief executive said: *'It is important to maintain an independent authority to safeguard patients' interests. It is thus important to ensure that the authority is sufficiently robust to exercise that authority and be resources effectively.'*

A Chief Executive and Head of Laboratory Services said: *'As a research scientist I know there is considerable benefit to the community in successful research but in your particular case this benefit rests on the belief that the HFEA has the ability to properly regulate research and treatment. Any perceived failure of regulation could easily undermine public and professional confidence.'*

Concern about duplicated functions

Several respondents were concerned that the HFEA's functions might duplicate those of other regulatory bodies e.g. National Care Standards Agency and Commission for Health Improvement. A licensed centre said: *'With the introduction of the National Care Standards, which for assisted conception sees to duplicate the HFEA Code of Practice, is there any merit in amalgamating the two bodies?'*

The National Care Standards Commission suggested that there were areas of potential overlap in activities in particular in registration/licensing, inspection, investigation of adverse events, and enforcement. Their response surmised: *'The implicit similarities with the respective regulatory remit of each agency, may be perceived by providers as an overlap of common functions, both increasing their work in making applications or preparing for ongoing inspection.'*

The NCSC noted that the differences in the respective responsibilities may be perceived to be insufficient to warrant the significant variation in fee structure between the two organisations.

The NCSC advised that their fees are:

Registration fees

£1,100 + £300 manager fee for the registration of an acute hospital

£300 + £300 manager fee for small establishments

Annual fees

£2,500 + £100 per registered bed for 4-29 beds (thereafter £50 per bed)

£750 (unspecified)

Variations

Minor variation £50

Major variation £550 (small establishments £300)

The NCSC concluded that: *'it will be important for the two agencies to work together to eliminate unnecessary bureaucracy or delay ... and to collaborate on areas of common function to effect efficiency and effectiveness for both providers and patients.'*

The Commission for Health Improvement advised: *As the National Care Standards Commission and the Commission for Health Improvement move into a new organisation, the Commission for Healthcare Audit and Inspection, it is important that relationships with*

the HFEA and CHAI are clear and we would support the drawing up of a memorandum of understanding between the appropriate bodies.'

Need for operational improvements

There was common agreement that the inspection process is cumbersome and it should be rationalised. Several responses remarked specifically on the need to improve the inspection process. *'Although inspection report forms are a change in the right direction, inspections still appear to be subjective.'* (licensed centre)

There was common agreement that providers lack confidence in the validity, consistency and comparability of clinics' results as collected as part of the licensing procedure. Some respondents said that more data is collected by the HFEA than is required by the HFE Act. However, another view was that the publication of results data is an important function of the HFEA, but that the cost of this should be supported by the DH. There was also concern from the RCOG and the BFS that data collected by the HFEA should be made available for research purposes.

Some concern was expressed that the processes at the HFEA had allowed such a serious funding problem to develop and that HFEA/DH had been (and continue to be) insufficiently open about the extent of the problems. A former vice chair of a health authority commented: *'My first thought is that this situation should never have been allowed to develop but I suppose it is too much to hope that anyone will be sacked or resign.'*

Another respondent observed: 'I believe you are right to wish to strengthen the HFEA's organisational systems and in particular I support your desire to improve quality assurance and risk management procedures. I believe it would be a matter of serious concern if the HFEA ever found itself in a situation where its level of funding was insufficient for its growing and increasingly complex workload.'

However, the view was also expressed that patients should not now be asked to pay for the past poor management of data collection and processing. A few responses suggested that the HFEA should consider relocating to cheaper, less central office accommodation.

The impact of increases on assisted conception services

Many respondents were concerned that any increase in fees should be sensitive to the budgets of smaller clinics and that there is a need for an impact assessment.

'Any further changes in increasing fees or timing of invoices should be phased over a period of e.g. two years so that units can put into place plans to cover the increased costs for the service. The charges should only reflect the cost base of direct patient care and clinic regulation.' (licensed centre) *'If the HFEA cannot successfully negotiate an increased contribution from the Department of Health then any increase in fees from clinics and patients should be phased in over a reasonable timescale and should acknowledge the needs of smaller clinics. Any increase in fees will lead to less money being available for treatment within the NHS.'*

National Infertility Awareness Campaign *'is not opposed to the principle of an increase in the clinic licence fee, but [is] very concerned at the magnitude of the proposed increase.'*

Many responses expressed concern that a fee policy needs to take into consideration the fragility of already under-funded NHS services.

One director of a licensed centre said: *'The licence fee increase will result in fewer clinics, loss of services and less choice for patients. The larger clinics will become more difficult to police because of sheer size, and will become monopolies. It will be difficult for new units to set up because of the significant investment required to obtain the initial licence. NHS units will have to curtail their already stretched services to fund the increase.'*

Several respondents felt the fees strategy should distinguish between NHS and private clinics. *'We should prefer to see a discounted fee for NHS clinics but standard fees in the private sector... If fees for NHS clinics are to be substantially increased, this is a cost*

pressure requiring central recognition in NHS funding. This is especially important if NICE issues guidance which leads to a more universal pattern of assisted conception across the country.'

One PR stressed that within the NHS budgets are fixed a year in advance. A provisional response from the clinical and financial directors suggests that: *'They will not be prepared to meet this increased expense, unless it is paid for by our local Strategic Health Authority. The Strategic Health Authorities have only just been properly established and are not prepared to enter into discussions about increased services for any services at the present time or for the current financial year.'*

However, some respondents expressed understanding that the current income generated from fees is inadequate. A chief executive observed: *'I expect there will be concern expressed over the increase in the fees proposed but there are resilient arguments to support the proposal, for example: the fees can be compared with the revenue stream and profit margins of the providers; similar comparisons can be made with the charges applied by the NCSC; it would be inequitable for the costs necessary to run the HFEA to be raised from the general healthcare budget.'*

RESPONSES TO CONSULTATION QUESTIONS

12 of the responses, including the collective responses, declined to answer any of the questions put. Several responses indicated that in any event the fee is likely to be passed on to the patient.

The BFS response indicated: *'We accept that changes are necessary and that these may incur costs. We believe, however, that clinics should only accept an **appropriate and proportionate** increase in costs to cover regulation of activities providing this does not adversely affect the current levels of provision of IVF cycles...'* (bold in the original). The Society felt unable to *'approve the proposed increase in fees as we have insufficient evidence to make an informed opinion.'* The Society was keen to see evidence that the administrative problems within the HFEA had been addressed and wished to review the business case. Several other responses indicated that the HFEA needed to present and justify a business case for an increased budget.

The joint response from Patient's Groups recommended that the decision on fee levels be deferred until Government has decided how to implement NICE Guidelines on infertility services.

Of those that expressed an option

Q1. Which option is the most appropriate means of raising the HFEA income that is required to support its regulatory function?

26 preferred Option 1 (introduction of new much increased licence fees that would align fees with the cost of providing services)

9 preferred Option 2 (present system but with higher treatment fees)

In general those choosing Option 1 did so to lessen the feeling of the charge being seen as a tax on patients – although there was widespread concern that the increased cost would be passed on.

Those preferring Option 2 felt that Option 1 would put a disproportionate load onto small clinics where patient numbers are too small to spread the increased cost of the licence. Several responses suggested that NHS commissioning arrangements would be unable to cope with the introduction of an annual fee that they had not budgeted for. One Person Responsible for a licensed centre suggested that *'The HFEA should be transparent with the public and make it clear that £100 (IVF) and £50 (DI) are necessary to continue this regulatory function which is essential for quality assurance'*.

A consultant in Community Gynaecology & Reproductive Healthcare said: *'Option 1 requires careful administration by both the NHS and local clinics with a vast increase in administration time ... As a worker in the NHS Option 2 would seem more attractive as*

there would be less bits of paper demanding extra money floating around. I think it is unlikely that extra money will come from Primary Care Trusts to support these new fees and no matter how this subject is dressed up it will be a "patient tax".' This response also suggested that arrangements should be made specifically with Strategic Health Authorities or 'for central funds to support this work'.

While responding to the other questions, the RCN Fertility Nurses Group said that the *'proposed increase in payment is unacceptable within the proposed time frame'* and proposed *'that it would be preferable to pursue an alternative funding strategy'*.

One respondent suggested: *'A compromise between option 1 and option 2 should be considered. Modest application fees geared to the complexity of services proposed could be linked to annual inspection fees that were based on case load (or the number of items refrigerated in storage only centres.'*

Option 2 was supported by almost all those respondents involved in the provision of services.

Q2. Views were sought on whether it would be preferable to have a modified approach, to provide lower fees for small clinics with compensating fees for large clinics.

9 responses were content with a fixed fee structure
26 responses preferred a modified fee structure

Those in favour of the fixed fee structure felt it would be simpler. Those in favour of a more modified structure thought that *'smaller clinics should be paying less'*

'The Royal College of Midwives advised: 'In the RCM's opinion the fee structure for clinics should be modified and those clinics that are obviously "wealthier" in terms of resources, patients and number of cycles, that will presumably create more work within the HFEA should therefore pay more. Equally those clinics doing less should pay less.'

A number of responses noted that it would be appropriate to develop an algorithm to align fees with levels of activity.

A Health Authority chairman, whilst choosing a modified fee structure said: *'Whilst we support a modified fee structure in principle, this should not be done at the expense of quality. Small clinics should only do those procedures which can be done at least as well in a small clinic as in a larger clinic. We would be concerned if any proposals for a modified fee structure resulted in low volume work, in effect, being subsidised.'*

Q3. Who should pay the cost of regulating research licences?

11 responses preferred the cost of research licences to continue to be funded from other fees
22 responses preferred a more focussed fee structure

Some respondents had noted that this would be the subject of a future discussion and so did not wish to comment at this time.

The prevailing view was that the costs of regulating should be met by those centres involved in it and that research grants would need to take this into consideration. Some responses suggested that Government should meet the costs of research regulation. One Clinic director said: *'The regulation of research licenses should be separated from clinical activities. Why should the infertile pay for research such as that into stem cells that may have commercial benefits in unrelated areas? Licences must be sought for research but should be granted without charge to facilitate the advancement of knowledge. The Government must fund this aspect of HFEA to further the wider national interest.'*

An alternative view was: *'Research is an integral part of medical practice and the cost of licensing projects should be shared between all licensees. Applications for research should not have to include the cost of HFEA approval.'*

Q4 How could the HFEA develop its practices to meet more effectively the needs of the clinical and scientific communities, patients and policy makers.

There is a high awareness among service providers that improvements must be made to the functioning of the Authority.

'Service providers lack confidence in the HFEA partly due to mis-management of data sent in by the Centres...The admission of the HFEA that it was not possible to produce a Patient Guide is unacceptable in that Centres were unaware of the extent to which the HFEA was not coping. Service providers are also aware of the extremely high turnover of staff within the HFEA, which does not give confidence in the system. There is little transparency in the services provided by the HFEA.' (licensed centre)

'We have seen evidence of the deterioration of the HFEA's resource base over the last five years and have witnessed many shortcomings in its ability to gather data supplied to it by clinics, due to problems with IT. Data sent by clinics sometimes gets lost, phones go unanswered, patients' queries are left unanswered and the lack of any sort of complaints procedure within the organisation all make us agree with you that changes are needed and needed quickly.' (licensed centre)

Changes that clinics wish to see were summed up by one Person Responsible for a licensed centre as follows: *'Faster responses to queries. A more streamlined and structured inspection process. Better training for regulatory managers as they often have a poor grasp of the regulatory process. Training for inspectors and vetting their knowledge of the regulatory process. Faster responses to inspections and requests for inspections. More support from the Authority on matters of interpretation of the regulations'*. Many of the responses referred to one or more of these issues focussing mainly on the following areas

- Executive staff – the HFEA should ensure that it has a human resource strategy to ensure that there are efficient, effective staff that will stay within the organisation and receive appropriate training.
- Business Plan – the HFEA should make public a clear business plan.
- Regulation – the HFEA should not duplicate other regulators.
- Data collection – the HFEA should simplify the current data collection process and ensure timely validation. There should be less paperwork that is more focussed.
- Inspection – Inspection teams should be 'professionalised' and organised by executive (staff) inspectors.
- Patient involvement – the HFEA should involve patients in the production of the Patients' Guides to ensure they reflect what patients wish to know.
- Transparency – the HFEA should be more transparent, collaborative and communicative

Conclusions

Respondents to the consultation document want the HFEA to improve its operations and business processes. Many of those involved in the provision of services are frustrated at what they perceive to be an inefficient and bureaucratic organisation that, at times, lacks professional standards.

Most respondents acknowledge that the HFEA budget is insufficient to provide a robust regulatory service. Although the RCOG questions the need for the level of regulation and believes it could be considerably rationalised, other accept that regulation is important to maintain confidence in services.

There is clearly confusion about what should be (and is) funded centrally by Government and what is funded by clinic fees. Responses suggest that many service providers do not know which HFEA functions the DH funds directly.

Although it is widely accepted that the HFEA needs to improve its business practices, there is resistance to the proposed increase in fees. This is because, in the absence of a detailed business case, there is doubt that a fee increase of this magnitude is required. The publication of a full business case may allay these concerns.

Action taken by the HFEA in response to this consultation

The Authority discussed a detailed Business Case on 26th September and agreed that major changes to the HFEA's functions were needed and that these would require additional funding.

Although a majority of individual responses to the consultation document supported the introduction of new licence fees (option 1), other responses – notably almost all from those involved in service provision - made it clear that this method of payment would be particularly burdensome for smaller centres and those reliant on NHS funding. The Authority was also persuaded that the costs of an increased annual licence fee would be passed on to patients and would not achieve the Authority's original objective of moving away from a 'patient tax'.

In the light of responses to the fees consultation document and additional consultation with Stakeholders the Authority decided to generate the additional income required to support regulation through an increased fee for treatment cycles.

To provide centres with maximum notice of the fees increase, the Chief Executive wrote to licensed centres on 1 October 2002 to inform them that, subject to the approval of Treasury, the HFEA fee due per cycle of treatment will increase from 1 January 2003.

- **The treatment fee for IVF will be £100 per cycle**
- **The treatment fee for DI will be £50**

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Respondents to the consultation

Group/Organisation Responses

Association of Clinical Embryologists
 British Fertility Society (on behalf of licensed units)
 Commission for Health Improvement
 Child – the National Infertility Support Network (comments from 14 members)
 Donor Conception Network
 Fpa (formerly the Family Planning Association)
 Joint response on behalf of Acebabes, Child – the National Infertility Support Network, Donor Conception Network,
 Issue – the National Fertility Association
 National Care Standards Commission
 National Council of Women of Great Britain
 National Infertility Awareness Campaign
 PROGAR
 Royal College of Midwives
 Royal College of Nursing Fertility Nurses Group
 Royal College of Obstetricians & Gynaecologists

Licensed Unit responses

Mr M M Afnan FCOG Assisted Conception Unit, Birmingham Women's Health Care NHS Trust
 Peter Brinsden MB, FRCOG Medical Director, Bourn Hall Clinic
 Ruth Curson, ACU, King's College Hospital NHS Trust
 Chaucer Hospital
 Richard Howell, Medical Director, Nancy Hallett, Chief Executive and Roger Sirnam, Finance Director, Homerton
 University Hospital NHS Trust
 Julian Jenkins, Clinical Director, Centre for Reproductive Medicine, University of Bristol
 David Joyce, MA, DM, FRCOG former director, Southmead Hospital, Bristol.
 Jason Kasraie, centre no 0148
 Dr Gillian Lockwood, Midland Fertility Services
 Alison McTavish, Nurse Manager, Assisted Reproduction Unit, Aberdeen Maternity Hospital
 Mr M S Obhrai, ACU, Newcastle
 J M Randall MD, MRCOG, Peterborough Hospitals NHS Trust
 Dr M Segal, North East London Fertility Service
 Dr B L Stein, Tower House Clinic
 Alison Taylor, Consultant, Guys & St Thomas'
 Mrs M Vobes, Service manager, Directorate of Obstetrics & Gynaecology, Grampian University Hospitals NHS
 Trust
 Mr Peter Wardle, Consultant Obstetrician & Gynaecologist, Directorate of Women's Health and Care of the
 Newborn, North Bristol NHS Trust

Individuals/Health care representatives

Dr P Datta, Redbridge PCT
 Dr Ann Farebrother, Shepway PCT
 Dr R F Fletcher, retired Vice Chair, West Birmingham Health Authority
 Professor Ivor Gaber, University of London
 Joan Greenwood OBE
 GP, PCT Commissioning
 Dr John Hayward, Director of Health Improvement, Newham PCT
 Ian H Jones, Chief Executive, British Pregnancy Advisory Service
 James Cook University Hospital
 N Khan
 Dr Diana Mansour, Consultant in Community Gynaecology & Reproductive Health, Newcastle Primary Care Trust
 Professor Elaine Murphy, Chairman, North East London Health Authority
 Paul Nurse FRS, Chief Executive, Head of Cell Cycle Laboratory, Cancer Research UK
 Mr David Paintin FRCOG
 A Patient
 Primary Care Trust
 Dr B C Patel
 John Raywood
 Dr Rental
 Dr Ainsley Reid, Chairman, Dyfed Powys Health Authority
 Margaret Robinson, Thurrock Primary Care Trust
 M. Sauntoo
 Mary Sidebotham MA, RM, RGN, DPSM, ADM
 Dr Robert Wilson, Director of Public Health, West Lincolnshire PCT