Rationing Policies on Access to In Vitro Fertilisation in the National Health Service, UK

Aurora Plomer, Iain Smith, Norma Martin-Clement

This paper reports on a study of the local policies and specific rationing strategies for in vitro fertilisation (IVF) adopted by Health Authorities in England and Wales. All Health Authorities in England and Wales were asked for this information and a representative sample then took part in a follow-up interview. A majority of Health Authorities had adopted formal eligibility criteria in order to fund access to IVF treatment. These criteria were both overt and covert, and ranged from the clinical to the social. They included infertility, age limits, number of children, status of the couple and sexual orientation. Social criteria tended to exclude from public funding individuals who were not in a stable heterosexual relationship. We found a multiplicity of approaches which were not necessarily consistent with each other nor based on the purported goal of promoting clinical and cost effectiveness. Some policies were discriminatory against certain categories of women. Further, there appeared to be a discrepancy between some Health Authorities’ exclusion policies and the 1990 legislative framework on access to IVF treatment in the UK.

The technique of in vitro fertilisation (IVF) has been available since the late 1970s to assist couples unable to conceive by natural means.1 In the 1980s IVF remained largely experimental and was conducted almost exclusively in the private sector, with each cycle of treatment costing upwards of £2,000. In the late 1980s and early 1990s a small number of National Health Service (NHS) clinics began to fund treatment.2 The numbers steadily increased in the mid-1990s with the latest surveys in 1997, showing that two-thirds of Health Authorities were funding the service. The budget allocated, however, tended to be small and a majority were using formal eligibility criteria to select patients.3 In this respect, formal and explicit rationing strategies for IVF were unusual; no significant move from implicit to explicit rationing had occurred for the majority of treatments between 1992 and 1996.4

We carried out a survey to find out from Health Authorities themselves the reasons behind the adoption of specific rationing criteria and the factors which had prompted them to develop rationing policies on IVF.

The context of health care rationing in the UK

The National Health Service was created after World War II with the aim of providing a free, comprehensive and universal health service ‘available to all people’ and covering ‘all necessary forms of health care’.5 Although it was hoped at the time that the demand for health care would diminish as the health of the nation improved, the inescapable logic was that if the assumption did not prove right then hard, even ‘tragic choices’6 regarding the priority ranking of treatments would have to be made.

In practice, and until the 1980s, rationing took place to a limited extent at a macro level in the distribution of resources to the Department of Health and to Health Authorities by central government, and more significantly and mostly implicitly at local or micro level by health care professionals delivering services.7 All this was to change by the early 1990s, when the new political orthodoxy came to see problems of scarcity as the product of waste rather than underfunding.8 Efficiency was formally adopted as a guiding
principle for the NHS\textsuperscript{7} and came to embrace not only managerial decisions on resource allocation\textsuperscript{8} but the enhancement of clinical practice, which was to be based on systematic, scientific evaluation of the clinical effectiveness of interventions.\textsuperscript{9}

The administrative changes were completed by legislative changes in 1990 (National Health Service and Community Care Act 1990), literally splitting the NHS into ‘purchasers’ and ‘providers’, to facilitate the introduction of an ‘internal market’. This consisted of a system of contracting of services by purchasers (Health Authorities and GPs) from providers (NHS trusts). Health Authorities were now required to develop annual local ‘purchasing plans’. These plans were to be based on an assessment by each Health Authority of the health needs of the local population.\textsuperscript{10} Resources were to be spent ‘on high quality, value-for-money services’ through contracts with providers. Consequently Health Authorities had to determine which services to prioritise. Rationing, which had previously taken the form of patient selection at the point of service delivery, shifted to a meso level to Health Authority managers, who now had the responsibility of distributing resources by ranking treatments on the basis of their clinical and cost-effectiveness.\textsuperscript{9}

The priority generally accorded to IVF was unsurprisingly low. IVF was typically targeted for exclusion alongside tattoo removal, cosmetic surgery and buttock lift, treatments which were deemed to be insufficiently urgent to warrant claims on the public purse.\textsuperscript{11} Alternatively, when funds were allocated for IVF treatment, IVF came at the bottom of the priority list and the budget allocations were insignificant. In addition, there was evidence that these limited budgets came with strings attached, as Health Authorities began to stipulate eligibility conditions for treatment.

**Results**

The documentation which was sent to us by Health Authorities in response to our letters varied tremendously, both in its content and format, in line with other surveys.\textsuperscript{4} Of the 101 HAs who responded to our original letter, 17 (17 per cent) said that the policy was under review, two were using provider-derived protocols, two used the ad hoc advice of the Department of Public Health on a case-by-case basis, one used only presence on the waiting list as of April 1993, and one had protocols under review. Of the remaining 78, 17 (22 per cent) had a clear policy of not funding IVF treatment. Thus, 61 responses could be analysed for any guidelines that were being used to define patient eligibility.

The rationing factors most commonly mentioned by the 61 HAs who were prepared to fund IVF treatment were these:

- infertility of the woman or couple
- woman’s age
- male partner’s age
- children from existing relationship
- children from past relationships
- marital status or relationship
- sexual orientation
- the welfare of the child.
Additional criteria mentioned included:

- woman must be able to produce her own eggs;
- both partners must be able to produce suitable gametes;
- couple must be prepared to accept donor sperm;
- partner's Body Mass Index;
- woman's body weight;
- smoking;
- place of residence; and
- neither partner is HIV positive.

For the most commonly cited rationing factors, the combined results of responses in both phases of the study yielded the following results.

Infertility

Infertility commonly appeared as a threshold condition, triggering further criteria limiting eligibility for treatment. Thirty-four authorities expressly said in the literature submitted that they were prepared to fund IVF treatment only to treat infertility. Of these, some had gone to great lengths to establish detailed clinical protocols on the diagnosis of infertility, whilst others had none. Infertility was typically defined by reference to a specified period of time during which a couple seeking treatment were to have been trying and failed to conceive. But there were significant variations in the specified periods of time, which ranged from one to five years, with the majority stipulating a two- or three-year period (see Table 1).

In the interviews, HAs found it difficult to justify the precise period of time they stipulated. One HA, who required a couple to have been trying to conceive for three years recognised that this was longer than the period of two years in the World Health Organization's definition of infertility. It justified this on the grounds that 10 per cent of couples may still conceive after two years and the time to do tests required to establish infertility would stretch the two-year period to three years (HA11). Another HA required couples to have been trying to conceive for two years after their initial visit to their GP, although it advised couples in its public information leaflet to visit their GP after one year of unsuccessful attempts (HA10). Some health authorities had erred on the generous side by choosing a 12-month period 'as an arbitrary cut-off' even though 'there is still a percentage of couples who will conceive after 18 to 24 months' (HA17). Some opted for a period of 12 months as the 'correct' point at which to begin simple, first-line advice from the GP (HA1). Some relied on the guidelines in the 1992 Effective Health Care Bulletin (HA9), whilst others left the decision to the referring GP or the provider unit (HA19).

Even when they considered that infertility was established, some HAs imposed further restrictions on eligibility for treatment, depending on the causes of infertility. One HA only funded cases where infertility had caused severe anxiety or depression (HA15).

Some HAs provided anecdotal evidence that social factors were being taken into account by clinicians in deciding whether infertile patients deserved treatment, e.g. 'Funding may well not be given to treat a woman who appears to be very promiscuous and poor but given to treat a church-going pleasant middle class lady who seems to have no apparent reason for infertility in a stable relationship' (HA12). It was thought that patients were less likely to receive funding if they were perceived to be 'responsible for their own problem, for having caused their infertility', even though such 'moral and ethical judgements' were not likely to figure expressly in the priority rating (HA15).

Infertility still figured as a de-facto threshold for treatment for the vast majority of the HAs who had not expressly mentioned it in their documentation, as they restricted treatment to (heterosexual) couples married or in stable relationships who had no children from the existing or previous relationships.

Table 1. Length of infertility to be eligible for IVF treatment (34 Health Authorities)

<table>
<thead>
<tr>
<th>Number of responses</th>
<th>1 year</th>
<th>2 years</th>
<th>3 years</th>
<th>4+ years</th>
</tr>
</thead>
<tbody>
<tr>
<td>5*</td>
<td>18**</td>
<td>10*</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

* One HA used either 1 or 3 years depending on the woman's age.
** Two HAs used 1.5 years.

Woman's age

Of the 61 responses from HAs with eligibility criteria, 54 (89 per cent) mentioned a specified age limit for treatment. All had an upper limit, which ranged between 34 and 50 years, the
commonest age being 40 (n = 13). Of the 16 who mentioned a lower age limit, the specified age varied from 20 to 29, with the commonest being 25 (n = 11).

The setting of an upper age limit tended to be justified on grounds of clinical effectiveness. (HAs 5, 10, 14, 15, 16, 17, 20). One HA cited recent articles in the BMJ and Lancet to support an age limit of around 35-37 (HA4). But whatever the age limit set, reasons other than clinical effectiveness were also involved in setting that limit. In one HA, the maximum and minimum age for both partners was arrived at from the consensus shown by GP questionnaires and the effectiveness of the treatment, although the exact cut-off point was admitted to be arbitrary (HA15). Another HA described its choice of 35 as ‘an arbitrary decision based on pseudo-evidence’ (HA7). In one HA, the age limit was originally set at 42 but one consultant wanted it to be 38 (HA2). It was then set arbitrarily at 40, which was thought to be acceptable to the informed man-in-the-street. One HA set the age limit at 40, although it was felt that on purely clinical considerations, it ought to be 25-30 (HA1). In another HA, an upper age limit of 35-37 was originally considered, but age 35 was chosen on the grounds that the numbers of women coming forward for treatment would thereby be reduced (HA4).

The setting of minimum age limits appears to have been based on grounds other than clinical effectiveness. One authority justified this on the grounds that the final budget would be small and, therefore, people’s hopes would not be raised when they could not be fulfilled (HA4). Another admitted that ‘There is no actual biological reason... It was a social thing rather than a biological one’ (HA7).

Male partner’s age
Fourteen of the 61 HAs with eligibility criteria (23 per cent) mentioned a specified age limit for the male partner. One HA set a minimum age limit of 25 years. All had an upper age limit of between 35 and 55. The commonest upper limit was <50 (n = 5).

Only two of the 15 funding HAs who were interviewed had an age limit for male partners. One said that the upper age limit was a mixture of social and biological reasoning as ‘there is some evidence that male reproductive function deteriorates with age and also a large age gap between parent and child did not seem appropriate’ (HA15). The other described it as a value judgement: ‘part of the process of seeing what was sensible’ (HA5). Amongst those which did not have an age limit for the man, one expressly justified this on the grounds that clinical effectiveness was not affected (HA10).

Children from the current relationship
Forty-eight of the 61 HAs (79 per cent) mentioned the presence or absence of children in the current relationship as an important factor. Of these, 44 (92 per cent) required that the woman should have no children with the current partner. Three were prepared to provide treatment where the couple already had one child. Two would only do so if the child was under age 2 in the one case and under age 16 in the other.

Several HAs cited equity or fairness as a reason for restricting treatment to couples with no children in the current relationship (e.g. HAs 8, 14, 16, 18). The common aim was to meet a health need, depicted in the mechanistic language of one Health Authority as ‘helping a uterus to work if it has not worked’ (HA8).

The interviews established that HAs were conscious that the ‘no-children’ criterion for inclusion was a social rather than clinical criterion (HAs 7, 11), but one thought this was supported by social consensus (HA11).

Children from previous relationships
Thirty-seven (61 per cent) of the 61 HAs mentioned children from previous relationships as an excluding factor. Of these 37, 34 (92 per cent) required that there should be no such children. Only two of the 37 were willing to consider a couple when there was one such child. Against the trend, one HA actually looked favourably on applications from couples with children in previous relationships on the advice of the gynaecologist provider, who took the view that clinical effectiveness would thereby be enhanced (HA17).

The policy of excluding those with previous children tended to be justified on utilitarian grounds: ‘There is only a very limited resource and this is an attempt to spread the benefit of having a child as widely as possible’ (HA16). But in the interviews, several HAs expressed difficulties with this criterion. One mentioned that the exclusion of children from previous relation-
ships ‘is now causing problems because people who have had a family and then been sterilised in a previous relationship are now requesting IVF’ (HA17). Another HA was finding it difficult to justify its policy in cases where the previous child of one partner did not live with the couple, although they had still decided not to alter their policy (HA5).

**Relationship between partners**

Thirty-three (54 per cent) of the 61 HAs with eligibility criteria expressly mentioned in their documentation that they were only prepared to treat couples. A small minority (3 of the 33) expressly required the couple to be married. Almost two-thirds of the 33 (64 per cent) required that the relationship be stable but not necessarily based on marriage. Altogether 73 per cent of HAs restricted treatment to couples who were either married or in a stable (heterosexual) relationship. However, the actual percentage of HAs limiting access to these couples is likely to be even higher as information supplied to us by HAs in their own documentation varied tremendously. Furthermore, other rationing factors such as infertility had the same limiting effect, albeit in an indirect manner.

Of the three HAs who required couples to be married, two did not prescribe a minimum number of years of marriage; one required the couple to have been married for at least three years. By contrast, the stability of relationships tended to be assessed by the number of years the couple had been together, which varied between one and three years, with six HAs requiring at least two years and eight requiring three years together.

The reasons given in the interviews for including couples only varied from concerns over the welfare of the child to a deliberate attempt to exclude single women and lesbian couples: ‘Restricting treatment to couples was a definite policy decision based on the welfare of the child’ (HA7). One HA stood out in the interview for having decided to concentrate on the infertiltiy problems of women only: ‘women all the way, we left the men right out of it’; this was because the Authority did not want to get involved in questions of ‘what is a couple’ or ‘about lesbian couples’ (HA8).

Another HA had opted for providing IVF treatment on an ad-hoc basis only for patients in exceptional medical circumstances (e.g. cancer of the ovaries) as they did not want to use social criteria; they regard this as ‘pernicious... because you start to make quite major value judgements’ (HA6).

**Sexual orientation**

Sexual orientation was also specifically mentioned by several HAs in the documentation sent to us. A significant minority 9 of 61 (15 per cent) expressly limited funding to couples who were in a stable heterosexual relationship. But the qualitative interviews suggested that exclusion on grounds of sexual orientation was more widespread and tended to operate indirectly.

One HA, who had no written policy restricting funding to heterosexual couples, nonetheless described its policy as deliberate (HA16). A request for treatment from a single women had been refused and whilst there had been no requests for treatment from lesbian couples and ‘no real decision has been made, the DPH... would be inclined to refuse to fund treatment’ (HA16). One HA who had no specific written criteria said, when prompted on its views during the interview, that ‘no doubt the relationship would have to be heterosexual rather than homosexual’ (HA12). Another said that one consultant was known only to treat heterosexual couples (HA13). One HA, who had not considered the question, thought that it would have to go back to the Board (HA4) and another said that whilst ‘the question of homosexual couples was not even considered...a single woman or lesbian couple would not qualify for treatment’ (HA7).

One HA had consciously excluded lesbian women by default as ‘the requirement for a stable marriage or two-year relationship would exclude single women’ (HA3). Another had consciously excluded lesbian couples as ‘they are not by definition infertile since infertility requires heterosexual sex without success for one or two years, so they would not be eligible for infertility treatment because they are not infertile’ (HA2).

As one HA, who had dropped a previous requirement to restrict treatment to heterosexual couples candidly admitted, the same result could be achieved by relying on the definition of infertility alone (HA2). Alternatively, IVF treatment was de facto restricted to heterosexual couples if the Authority did not fund donor treatment (HA14).
Those excluding non-heterosexual relationships described them as an ‘unnatural bond’ (HA15) or failure to provide a ‘secure family background’ (HA16). One HA thought that unequal treatment of lesbian couples was justified on the grounds that ‘there are so many normal couples in whom there is a functioning male that one could not get through all of them... If people have the bad luck to have other problems it does not necessarily mean that they have to be treated on an equal basis’. By contrast, one HA, which had used to treat heterosexual couples only, decided to remove the exclusion as it was thought that the welfare of the child would be a more appropriate guiding principle (HA11). Another, which had expressly sought to exclude single women, had nevertheless deliberately refrained from specifying the sexual orientation of the couple, as it was thought that the number of gay couples likely to want treatment would be so small that there was no need to exclude them (HA20).

The welfare of the child
The welfare of the prospective child was cited by a significant minority of the 61 HAs as a guiding principle for exclusion 16 (29 per cent). One HA relied on the welfare of the child as the only ‘absolute’ criterion: ‘We are not helping couples who are probably not fit to be parents’ (HA1). In some cases restricting treatment to couples was said to be ‘a definite policy decision based on the welfare of the child’ (HA7). In addition to the status of couple and sexual orientation, the welfare of the child was sometimes used to justify other exclusion factors such as HIV (HA2), drug abuse (HA3), child abuse or violence (HA10), or smoking (HA15).

A minority had deliberately refrained from adopting a formal policy on the welfare of the child and left the decision to the provider (HAs 9,14,20). Only one HA appeared to be aware that the clinician providing the treatment was already under a legal duty to consider the welfare of the child (H14).

Health Authorities who would not fund IVF
The reasons given by HAs who did not fund IVF were threefold. First, when compared to all other health care priorities, IVF was considered to be of low priority (HAs 8,13,19). One HA estimated the extra cost of funding IVF to be of the order of £500,000 per year; if they had this extra money they said they would rather spend it on cancer care (HA6). Second, non-funders were not convinced that IVF was an effective treatment (HA6) and were prepared to invest in some infertility services but not IVF (HAs 8,13,19). Finally, they were uncomfortable with the use of social criteria for the allocation of scarce resources: ‘Our job is not to give you a child or a child in your home or a child with this partner as opposed to any other partner’ (HA8).

In summary, amongst the HAs who had chosen to fund IVF treatment, the main findings which emerged were these:

- a majority had adopted formal eligibility criteria;
- the eligibility criteria ranged from the clinical to the social;
- although there was convergence in the choice of formal clinical criteria, such as infertility and age limits, there were considerable variations in the detailed specification of these criteria; and
- there was convergence on the choice of social criteria such as number of children, the status of the couple or sexual orientation. Social criteria tended to exclude from public funding individuals who were not in a stable heterosexual relationship. The exclusion factors operated both overtly and covertly.
ians to determine who should receive treatment on the basis of the welfare of children; specifically, the Act says [Section 13(5)] that in determining who should receive treatment services providers are required to take into account:

'...the welfare of any child who may be born as a result of the treatment (including the need of that child for a father), and of any other child who may be affected by the birth'\(^{22}\)

The original bill carried no qualifications on eligibility for treatment.\(^{22}\) Section 13(5) was inserted in response to various moves to amend the bill by members of Parliament whose motivation was to exclude individuals from treatment on the basis of their marital status and/or sexual orientation.\(^{23}\) But the actual wording contains no such exclusion. Furthermore, the statutory Code of Practice drawn up by the HFEA, to provide guidance to clinicians for assessing those who seek treatment, bears no support for such blanket exclusions. Instead, the Code of Practice requires licensed IVF centres to bear in mind:

- their commitment to having and bringing up a child or children;
- their ability to provide a stable and supportive environment for any child produced as a result of treatment;
- their ability to provide a stable and supportive environment for any child produced as a result of treatment;
- their ability to meet the needs of any child or children who may be born as a result of treatment, including the implications of any possible multiple births; and
- the effect of a new baby or babies upon any existing child of the family.

There is a notable degree of overlap between these criteria and those adopted by several HAs, and some criteria, e.g. age limits or the requirement of marriage or a stable relationship, could be construed as indicative of an applicants' ability to meet the HFEA conditions. But there are crucial differences between the formal criteria adopted by HAs and the factors listed in the HFEA Code of Practice.

First, the Act requires clinicians providing the service to assess the suitability of each individual patient. By contrast, some HAs' policies operate so as to exclude whole categories of patients, regardless of their individual circumstances.

The Human Fertilisation and Embryology Act 1990: legal considerations

It may be argued that the use of social criteria to determine who should receive IVF treatment is in any event required by the Human Fertilisation and Embryology Act 1990. That Act allows clinic-
Secondly, the factors listed in the Code of Practice are not supposed to operate as rigid criteria. Instead, they constitute evidence of the woman's/couple's ability to meet the needs or welfare of the prospective child; they are not intended to be applied in an all-or-nothing manner. Clinicians are required to use their discretion, whilst the highly specific eligibility criteria drawn by some HAs do not allow them to do so. Under the Code of Practice, clinicians may not automatically rule out a patient who happens to be single or has children from previous relationships. The relative weight of various factors has to be assessed by reference to each individual's circumstances.