Implementation of the NICE Guideline - Recommendations from the British Fertility Society for National Criteria for NHS funding of Assisted Conception

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Summary

Assisted conception providers in England were surveyed to establish the uptake of NICE Guidelines for Infertility particularly in respect of assisted conception and the criteria used to accept patients for NHS funded treatment. Detailed information on selection criteria was obtained from a group of commissioning consortia at an advanced stage in their arrangements. While there was an overall increase in the number of NHS IVF cycles purchased in England, implementation is stalled at one fresh cycle in the vast majority of Primary Care Trusts (PCTs). There is little consensus about the criteria used for acceptance into an NHS programme. This is particularly so in respect of social criteria which are often arbitrary and used as a rationing tool. This information complements that provided by the survey of Primary Care Trusts performed in March 2005 by the All Party Parliamentary Group on Infertility (APPGI) in partnership with the National Infertility Awareness Campaign (NIAC) which together provide a basis for recommendations for NHS funding. The recommendations presented should be applied across England and Wales to ensure consistency, fairness and equity of access.

Key Words: *NICE Guideline on Infertility; definition of infertility; clinical criteria; social criteria; NHS Commissioning*

Introduction

The hopes and expectations of the infertile were substantially raised in February 2004 with the publication by the National Institute for Health and Clinical Excellence (NICE) of their fertility clinical guideline (NICE, 2004) www.nice.org.uk-pdf-CG011niceguideline.pdf.url. When published, the NICE Guideline placed NHS assisted fertility services firmly in the mainstream of state funded healthcare, but after two years the NICE recommendations on assisted conception treatment show little sign of becoming reality (APPGI/NIAC, 2005), in contrast to the situation in Scotland where a national commissioning strategy has been in place for several years (EAGISS, 1999; Scottish Executive, 2000 and 2005).

The NICE Guideline was commissioned by the Department of Health and the National Assembly for Wales because of disparity and inequity in the provision of infertility services in England and Wales; the so-called postcode lottery. The Guideline made explicit reference to the effect of female age and weight on the outcome of infertility treatment. However, no recommendations were made for the use of non-clinical or social criteria in the provision of treatment. In any healthcare system there are limits set on what level of service is available. Primary Care Trusts (PCTs) have a complex task to commission within available resource whilst balancing this with individuals' rights of access to a range of health care particularly when new treatments are developed. According to the results of the survey of assisted conception providers, commissioners across England have applied a range of social criteria to inform funding decisions, most without evidence and almost all used as rationing tools. Furthermore, there appears to be little consensus on the application of these non-clinical criteria. This lack of consensus has maintained inequity of access to NHS funding of assisted reproduction in England (APPGI/NIAC, 2005).

One of the key recommendations of the NICE Guideline was the provision of up to three fresh cycles of In Vitro Fertilisation and the replacement of the frozen embryos resulting from these cycles. The recent survey by the All Party Parliamentary Group on Infertility in partnership with the National Infertility Awareness Campaign has shown no indication that this recommendation has been implemented, indeed, there is evidence of reduced funding by some PCTs who previously funded two or three fresh

cycles (APPGI/NIAC, 2005). Data on the funding of frozen embryo transfer cycles was not provided in the APPGI/NIAC survey although our own findings indicate that few PCTs have included this in their commissioning. To investigate progress in implementation and the criteria for access to NHS funding, the British Fertility Society recently conducted a questionnaire survey of IVF providers. While this shows an overall increase in the number of NHS funded IVF cycles, there remain areas in England that have no NHS funding for IVF and some with only a token gesture toward implementation. The survey also shows that almost all PCTs are funding no more than one IVF cycle, and confirms that in some cases there has been a reduction. Moreover there is no clarity on the definition of a funded cycle. The recommendation in the NICE Guideline is that a funded cycle should include ovarian stimulation and the replacement of fresh embryos and the subsequent replacement of frozen-thawed embryos generated by the ovarian stimulation episode. There is no consistency in the application of this definition by funding commissioners. Furthermore the variation in application of non-clinical criteria is confirmed.

This paper presents the findings of this survey, together with a review of the detailed commissioning arrangements from six PCT consortia and makes recommendations for *National Criteria* to access NHS funding. The recommendations are supported by INUK, the national infertility patient organisation.

Methods

A questionnaire was circulated electronically in May 2005 and again in July 2005 to all centres in England licensed by the Human Fertilisation and Embryology Authority (HFEA). Details of licensed centres were obtained from the 2005 HFEA Patients Guide. The questionnaire was also available on the British Fertility Society Website. The results were analysed by one of the authors (RK). In addition, the detailed arrangements of six commissioning consortia involving 56 PCTs (Table 1) were available for detailed review.

Cheshire, Merseyside and West Lancashire
Solihull, Coventry and Warwickshire
County Durham and Tees Valley
Thames Valley and Swindon
North Derbyshire, South Yorkshire and Bassetlaw Commissioning Consortium
Bristol, Avon, Bath, NE Somerset, Gloucestershire and Worcester

Table 1: Commissioning groups providing detailed information

Results

Responses were received from 37 of 64 (58%) licensed IVF centres in England circulated. The responding centres provide 13,000 cycles per annum; nearly 50% of all IVF cycles performed in the UK. Of those responding to the survey, 21 (57%) were NHS based units providing a combination of NHS and self funding IVF; 6 (16%) were wholly private units; 5 (13%) were private units contracting NHS funded cycles; 5 (8%) were wholly NHS units; and 3 (8%) were university department based units. Of the 37 respondents, 31 had been involved in discussions with the PCT regarding implementation of the NICE Guideline.

Of those providing NHS services, 5 (16%) reported decreased provision, 9 (29%) reported no change and 17 (55%) reported increased provision for 2005/6. Almost a fifth (16%) of centres were not commissioned to provide intrauterine insemination (IUI). Ninety percent of centres were being commissioned for one fresh cycle with only half of these including the replacement of frozen embryos arising from the fresh cycle. Only 3 centres (9%) reported routine commissioning for two fresh cycles, and no centre was routinely commissioned for three. Three centres reported a variable level of commissioning across different PCTs with one centre reporting that one of their commissioning PCTs purchased three fresh cycles and the frozen embryos resulting from them (Table 2).

IUI	**No**	**%**
No information provided	10	32
No IUI	5	16
IUI unstimulated less than 6 cycles	7	23
IUI unstimulated = 6 cycles	5	16
IUI stimulated >/= 3 cycles	3	9
IVF		
No IVF	3	9
IVF 1 fresh cycle	12	39
IVF 1 fresh + frozen cycle	13	42
IVF 2 fresh cycles	2 (+2**)	6
IVF 2 fresh + frozen cycle	1 (+1**)	3
IVF 3 fresh cycles	0 (+1**)	0
IVF 3 fresh + frozen cycle	0 (+1**)	0

Table 2: **Range of assisted conception commissioning. ** represents those centres in which there is variation in commissioning arrangements between PCTs and in which at least one commissioned to perform more than 1 fresh and frozen cycle.**

A range of social definitions of infertility (childlessness) used to determine selection criteria for NHS funded treatment emerged from our review of commissioning consortia (table 3). There was no clear consensus and this was mirrored in our survey of assisted conception providers, which showed a small majority (48%) had NHS funding confined to those couples in whom neither partner had conceived a child. A significant minority (33%) were less restrictive being able to provide NHS treatment for those couples with no children living with them. A history of sterilisation in either partner emerged strongly as a criterion to refuse NHS funding with 70% of centres indicating that NHS treatment would not be available in such circumstances.

- Treatment offered only if there are no living children from the current or any previous relationship, including adoptive

- Treatment offered only if there are no living children from current relationship, including adoptive

- Treatment offered if there are no children of the couple including adoptive. Treatment offered if there are children from previous relationship but living elsewhere and denied access.

- Treatment offered if there are no children from current partnership including adoptive, but one partner must have no living children.

- Treatment may be offered if there are no children living in household, including adoptive.

- Treatment offered to couples where one or both partners have no living children from current or previous relationships

- Treatment offered to couples who have no children under 18 living with them

- Treatments offered to couples that have no children living in the household. This includes a child adopted by the couple or in a previous relationship. Once accepted for treatment, should a child be adopted or a pregnancy leading to a live birth occur, the couple will no longer be eligible for NHS funding.

Table 3: **Definitions of childlessness (social definition of infertility)**

More than half (52%) of the responses indicated a stable heterosexual relationship as a selection criterion while almost a fifth (18%) allowed NHS treatment irrespective of the partner's gender. In our detailed review of commissioning arrangements there emerged a clear majority who allowed treatment of same sex couples only if there was proven infertility in one or both partners, recommending that if one of the female partners was known to be fertile, consideration should be given to undertaking conception in the fertile partner. There was a clear consensus not to offer donor insemination as an NHS procedure to a woman in a same sex relationship who was not known to be infertile.

The most explicit criterion set by the NICE Guideline is age. Despite this, only 74% of respondents indicated that commissioning arrangements adhered to the NICE recommendation of 23 - 39 years. Although we did not include BMI and smoking in our survey of criteria, five out of six of the commissioning consortia required female partners to have a BMI between 19 and 29 at the time of treatment and two out of six required female partners to be non-smokers prior to treatment. There was marginal variation in the BMI value applied and one PCT group allowed for expansion of the BMI "gate" in female patients with a diagnosis of polycystic ovarian syndrome. Alcohol consumption in either partner, male partner's weight and whether the male partner smoked were not included in the commissioning criteria.

All respondents indicated that couples who had previously received NHS funding of IVF up to the limit of three fresh cycles specified in the NICE Guideline would not be eligible for treatment.

Discussion and Recommendations

1. Definition

The definition of infertility can be considered in both medical and social terms. Medically it is important, because of their differing prognosis, for commissioners to distinguish between unexplained infertility and that with a proven physical cause. The social definition of infertility is more problematic and is essentially used by

Commissioners as a rationing tool, based on the statement by the former Secretary of State for Health, Rt. Hon Dr. John Reid on the publication of the NICE Guideline, in which he stated that "……*I will be asking the NHS to give local priority to couples who do not have any children living with them*" (Department of Health, 2004).

The medical definition of infertility requires thorough investigation to be completed and can be defined:

a) In the absence of a pathological cause - "***the inability to conceive after 2 years in the absence of any physical cause and unprotected intercourse"***.

b) In the presence of a proven pathological cause – ***"the inability to conceive over a limited time period due to a physical cause"***

The timing of initial assessment to establish a medical diagnosis is recommended in the NICE Guideline. We support these guidelines but draw attention to the need to investigate couples in whom the female partner is > 35 years promptly, because of the deteriorating success rates for treatment in this group. The implications of the NICE guideline for the management of unexplained infertility in older women are clear.

The social definition of infertility refers to the status of those seeking treatment with regard to any existing children conceived to either partner, their children's domicile and age and, in addition, the status of the couple's relationship; for example, same sex couples. We recognise that, in this regard, there are widely differing views in society and amongst healthcare professionals and that commissioners derive their definition primarily for rationing purposes. We conclude that:

Defining infertility in social terms is neither evidence based nor supported by clear consensus and recommend that:

Commissioners should acknowledge the lack of consensus in defining infertility in social terms and be explicit that the use of such criteria are primarily rationing tools.

The NICE Guideline makes no attempt to define infertility in social terms nor does it distinguish between primary and secondary infertility. Indeed there is considerable evidence for improved outcome following assisted conception treatment in women who have had a child compared to those with primary infertility (Templeton, Morris & Parslow, 1996). Recent national funding decisions in Europe have not excluded women who have had a child (Gerris, 2005). The former Secretary of State for Health did not discount treatment for this group when making a statement on the NICE Guideline although he indicated that "……*I will be asking the NHS to give local priority to couples who do not have children living with them"* (Department of Health, 2004). Furthermore there is sociological evidence for improved psychological and emotional wellbeing of children with a sibling (Tseng et al., 2000). We recognise that drawing a distinction between secondary infertility brought about by pathological reasons and that due to sterilisation is somewhat arbitrary and is largely pragmatic, founded on limited NHS resources. Attention is also drawn to the fact that some couples seeking infertility treatment, each of whom may have had children by previous partners, may present with complex social circumstances which may raise concerns about the welfare of the child. Furthermore, the fact that one of the partners has been sterilised may not lessen the justification for treatment in comparison, for example, if sterilisation has been undertaken by a female in the context of an abusive relationship. Nevertheless, a distinction can be drawn on the basis of "pathological" infertility being involuntary and therefore meritorious of funding. We therefore recommend that:

If the couple have no children they should qualify for NHS funding.

If either partner have a child/children from a previous relationship but not the current relationship, they should qualify for NHS funding provided there has been consideration of the welfare of the child.

Where funds permit, couples who already have a child from the current relationship and who have involuntary infertility should receive funding, though childless couples should have priority. Treatment in these cases should be provided on the same basis as those with no children.

2. Age

Age of the female partner

The NICE criteria are based on evidence of the efficacy of treatment at the upper age range and the reasonableness of an infertility diagnosis at the lower. Evidence from providers and commissioners across England and Wales supports the implementation of this age range and we see no reason to recommend otherwise.

However, clarity is required on three points, namely 1) The age point at which NHS treatment is no longer available, 2) The access to NHS treatment at the upper age range when there are long waiting lists and 3) The management of unexplained infertility in women who are 37 or older.

It is well known that efficacy of treatment decreases with increasing age of the female partner (HFEA, 2002) and we do not disagree with the application of a female upper age limit of 39. However it is important to be consistent about the point in the treatment and assessment at which the age limit is applied. The current Government target for waiting time for elective admissions is six months and we see no reason to treat IVF differently to other procedures such as tonsillectomy and varicose veins. To ensure consistency, no fresh treatment should be commenced after the 40th birthday of the female partner. In taking account of waiting times and current targets no patient should be accepted for treatment within six months of the 40th birthday of the female partner although PCTs should continue to fund treatment provided up to the 40th birthday of the female partner. Frozen embryos created from treatment carried out before the 40th birthday are unlikely to deteriorate in storage and, as there is no evidence that pregnancy rates resulting from their replacement lessen with increasing age of the uterus in which they are placed, there is no reason to apply an age restriction to this treatment.

Unexplained infertility is defined by NICE as the failure to conceive within 2 years of regular intercourse in the absence of known reproductive pathology (NICE, 2004).

The NICE Guideline draws attention to the significant possibility of spontaneous pregnancy in the third year in these cases (Collins et al., 1995). Our detailed review of commissioning groups indicates that the majority adhere to the NICE definition of 2 years duration of infertility before treatment but one group requires 3 years' attempts to conceive before agreeing to fund. This presents difficulties for couples who present with this diagnosis when the female partner is in her late thirties, particularly if there are long waiting lists as it is known that increasing female age worsens the prognosis in this group (Collins & Crosignani, 1992). Furthermore the low pregnancy rates generally achieved with unstimulated IUI, as recommended by NICE, raise the question of whether IVF should be considered as an alternative to IUI in cases with long-standing unexplained infertility in which the female partner is in her late 30s (Mathur et al., Personal Communication, 2006). We therefore propose a scaled approach to treatment according to female age for patients with unexplained infertility (Table 4).

<table>
<tr><td></td><td colspan="3">Duration of infertility</td></tr>
<tr><td>Age</td><td>6 – 12 months</td><td>> 1 year infertility</td><td>> 2 years infertility</td></tr>
<tr><td>37</td><td>Reassurance</td><td>Reassurance</td><td rowspan="3">6 x unstimulated IUI
or
3 x stimulated IUI.
Consider IVF as alternative</td></tr>
<tr><td>38</td><td>Reassurance</td><td rowspan="2">6 x unstimulated IUI or 3 x stimulated IUI.</td></tr>
<tr><td>39</td><td>6 x unstimulated IUI or 3 x stimulated IUI.</td></tr>
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Table 4: Scaled approach to management of unexplained infertility according to age of female partner and duration of infertility

Our recommendations in relation to age of the female partner are:

<u>Unexplained infertility</u>: phased age criteria as per table. <u>All cases</u>: no treatment cycle started after female's 40th birthday; no patient placed on the waiting list within 6 months of the 40th birthday of the female partner; no age limitation on the use of frozen embryos created during an NHS funded cycle carried out before the female partner's 40th birthday.

Age of male partner

Although there is evidence for declining fertility in the male with increasing age (Hassan-Mohammed & Killick, 2003), there is no evidence for reduced success rates in assisted conception with increasing age of the male partner (Paulson et al., 2001). The key issue is the longevity of the older male partner in relation to the upbringing of the child that results from treatment. We therefore recommend, other than consideration of the Welfare of the Child in line with the HFEA Code of Practice, that:

Paternal age is not included in criteria for acceptance in NHS programmes.

3. Sterilisation

The ease of access to male and female sterilisation and the relative success of techniques to reverse their consequences by surgical or assisted conception techniques has increased referrals to infertility clinics of couples wishing to extend their family after sterilisation. A history of sterilisation in either partner will normally mean one or both partners have existing children and as a consequence may affect their priority for NHS funded treatment on the grounds of the "social" definition of infertility. We recognise that, in a cash limited service, the exclusion of patients who have undergone voluntary sterilisation procedures is fair until full implementation of the NICE guideline for those who have had no children or involuntary secondary infertility, is achieved. We also believe that in the interests of equity, commissioners should apply the same criteria to the purchase of surgical sterilisation reversal (male and female) and assisted conception methods. These criteria should, exceptionally, be subject to

variation on an individual basis, for example, in cases of the death of a child after sterilisation or in cases of premature sterilisation in an abusive relationship. Our recommendation is that:

A history of sterilisation in either partner will normally exclude a couple from NHS funding of assisted conception or surgical reversal of male and female sterilisation although there may be exceptional cases where funding is agreed

It is also important to recognise the needs of trainees in reproductive surgery and therefore we recommend that programmes of surgical reversal of sterilisation be maintained in a limited number of specialist centres on the basis that such treatments are funded by the patient and undertaken in a situation that provides the opportunity for specialist registrars and subspeciality trainees to gain expertise in such techniques.

4. Female weight

Body mass index (BMI) in the woman has an effect on fertility and on the efficacy of infertility treatment. The NICE Guideline has made explicit recommendations on the management of anovulatory infertility when the female patient has a BMI > 29 and < 19 on the basis that reduction of weight in women with a BMI > 29 increases their likelihood of a spontaneous conception and their response to ovarian stimulation. It also recommends that patients are advised that a BMI outside this range is likely to reduce the success of assisted reproduction procedures. NICE further recommends that more research is needed to understand the effectiveness of assisted reproduction in relation to BMI. Commissioners have extended this recommendation to include BMI outside the 19 – 30 range as an exclusion criterion.

Whilst we agree with the NICE recommendations we question the inclusion of BMI as a funding criteria. Several authors report no adverse effect of BMI on IVF outcome (Lashen et al., 1999; Wittemar et al., 2000; Winter et al., 2002). A recent large Norwegian study of 5019 treatments of IVF/ICSI also showed no statistically significant correlation between BMI at either end of the range with IVF outcome although they did demonstrate a significantly decreased response to ovarian stimulation and increased usage of gonadotrophins (Fedorcsak et al., 2004).

Furthermore, it should be recognised that this group of patients are particularly prone to emotional and psychological difficulties, grappling with both body image and infertility, and a refusal to treat on the grounds of weight will further compound these problems. However, it must also be recognised that there is an increased likelihood of obstetric problems in women with a high BMI including an increased incidence of gestational diabetes, pregnancy induced hypertension, thrombo-embolism and post-partum haemorrhage (Ricart et al., 2005; Kanagalingam, 2005; Balen et al., 2006).

We therefore accept the NICE guideline but in addition recommend that management of patients with high BMI be pro-active, include dietary support, exercise programmes and possible referral for psychosocial support. Funding of this support should be included in the commissioning arrangements. Providing there is demonstrable compliance with such programmes a BMI upper limit currently accepted by anaesthetists as fitness for day case surgery seems more reasonable. We recommend that:

Women with a body mass index of < 19 and > 29 should be referred for advice from a dietician, warned of the risks in pregnancy, if appropriate, provided with access to exercise advice and offered psychosocial support. NHS funding of their treatment should be deferred until they demonstrate response to these interventions. If the menstrual cycle is regular and the FSH normal, assisted conception may be provided if the BMI is < 36.

5. Smoking

There was no consensus on the use of smoking in the female partner as a selection criterion with only half of the commissioners excluding smokers from NHS funding. There is evidence that smoking in the female partner (OR 0.72 (0.61-0.84) reduces pregnancy rates in assisted conception (Linsten et al., 2005). The evidence for an adverse effect of the male partner smoking on IVF outcome is less compelling (Klonoff-Cohen et al., 2001). A man or women who smokes and presents with infertility should be given advice to stop smoking. In particular, the female seeking treatment should be counselled as to the implications of smoking both on the outcome

of treatment and the pregnancy that might result from treatment. However we believe it unrealistic to exclude smokers from access to NHS funded treatment on the grounds that it would be very difficult to police. We therefore recommend that:

Smoking should not be an exclusion criterion but patients who smoke should be given advice about its implications. In addition, all smokers should be given the opportunity to be referred to a smoking cessation programme.

6. Previous treatment

There is consensus in our survey that PCTs should decline to fund treatment if couples have had previous NHS funded treatment. We disagree with the limitation of NHS funding to ***fewer than*** the three recommended in the NICE guideline but we support the limitation of further NHS funding if a couple has already received the current quota agreed by the local PCT. The survey suggests that PCTs will also decline NHS funding to those patients who have funded three fresh cycles of IVF themselves on the grounds that this is the maximum number of fresh cycles recommended by the NICE guideline. This guideline is based on cost effective arguments but, although the evidence indicates a declining pregnancy rate over successive cycles, the fall between the third and sixth attempts is slight and the data are based on treatments carried out during the mid 1990s (de Mouzon et al., 1998; Kovacs et al., 2001). In a multivariate logistic regression analysis, Minaretzis et al (1998) investigated a number of factors affecting IVF outcome including rank of cycle and showed no correlation with increasing rank. Opsahl et al (2001) examined outcome from sequential cycles of the same egg donor and found no decrease in outcome with increasing rank up to six donor cycles. A number of other state funded programmes in European Union states and Australia set no such limitation (Gordts et al., 2005). We do not agree, therefore, that those who have funded treatment themselves, irrespective of the number of cycles, should be denied NHS treatment, *providing there are no clinical reasons not to proceed*. We recommend that:

NHS funding should not be provided to those who have already received the number of <u>NHS</u> funded cycles currently supported by their PCT. NHS funding should be provided to those patients who have had previously self-funded treatment

irrespective of the number of cycles, providing the individual clinical circumstances warrant further treatment.

7. Same sex couples or single women

The findings from our review of a basket of Commissioning Groups indicates that the majority support the treatment of single women and single sex couples in whom there is a proven cause of infertility. Macallum and Golombok (2004) undertook a review of children conceived to lesbian couples and single heterosexual women and concluded that "being without a resident father from infancy does not seem to have negative consequences for children. In addition, there is no evidence that the sexual orientation of the mother influences parent-child interaction or the socio-emotional development of the child". This provides supporting evidence for the provision of treatment to this group of patients and we support this view. It has been suggested by several commissioning groups that, in the interests of consistency with infertile heterosexual couples, treatment should only be provided to same sex couples or single women on the basis of demonstrable infertility. It is suggested that, in the absence of any known cause for infertility, a number of donor insemination cycles should be undertaken initially without NHS funding before recourse to NHS funded assisted conception. We believe this view is discriminatory and discourages same sex couples from a responsible approach to managing their desire for a child. Such requests for treatment should be subject to the same "Welfare of the Child" assessment as for heterosexual couples. We therefore recommend that:

Single women and same sex couples should be eligible for up to six cycles of NHS funded donor insemination treatment provided assessment of the Welfare of the Child has been undertaken in line with the Human Fertilisation and Embryology Authority Code of Practice, 2004. After failed donor insemination treatment or in the presence of an indication for IVF allocation of cycles should be on the same basis as for heterosexual couples.

8. Waiting times for treatment

The Department of Health in England in its recent discussion document "Commissioning an 18 week patient pathway" (Department of Health, 2005) has made clear that infertility, in common with other forms of medical need, should be subject to the same rules of waiting targets as any other form of medical disorder. The NHS Improvement Plan specifically suggests that any stage in a patient journey should last no longer than 18 weeks. This applies both to waiting times for referral for assessment and to referral for treatment. We concur absolutely with this view and thus recommend that:

Patients presenting with possible infertility should be seen for assessment within the same number of weeks of referral as for appropriately staffed specialist services, in line with the standard for all other medical conditions. Furthermore patients should be able to undergo treatment for infertility, including assisted reproduction techniques, within the same number of weeks of referral to specialist centres, as is standard for all other medical conditions.

Conclusions

This survey provides a "snap shot" at a time of the current stage of implementation of the NICE Guideline on Infertility from a provider perspective. Whilst the overall increase in the number of cycles of IVF provided is to be welcomed there are still "black holes" of funding and only one fresh cycle is being purchased in the vast majority of cases. There is no indication of long term planning and the results provide no reassurance that full implementation will be achieved. There remains considerable disparity across England and Wales in the commissioning arrangements in respect of the range of social criteria applied for acceptance into an NHS programme, and in the use of body mass index and smoking in the female. If we are to see an end to inequity of access across the United Kingdom there must be an explicit plan for the provision of three fresh cycles of IVF and consistency in the criteria used for NHS treatment. The generic criteria proposed in this paper, if adopted by PCTs in England and Wales, would help standardise access but we must use the findings of this survey to pursue the goal of full implementation of the NICE Guideline.

SUMMARY OF RECOMMENDATION

1. In the absence of a pathological cause infertility is defined as: - "***the inability to conceive after 2 years in the absence of any physical cause and despite regular unprotected sexual intercourse"***.

2. ***Commissioners (PCTs) should acknowledge the lack of consensus in defining infertility in social terms and be explicit that the use of such criteria are primarily rationing tools.***

3. ***If the couple have no children they should qualify for funding.***

   If either partner has a child/children from a previous relationship but not the current relationship, they should qualify for NHS funding provided there has been consideration of the welfare of the child.

   Where funds permit, couples, who already have a child from the current relationship and who have involuntary infertility, should receive funding, though childless couples should have priority. Treatment in these cases should be provided on the same basis as those with no children.

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4. ***No treatment cycle should be started after female's 40th birthday; no patient place on the waiting list within 6 months of the 40th birthday but treatment funded up until the 40th birthday of the female partner; no age limitation on the use of frozen embryos created during an NHS funded cycle carried out before the female partners' 40th birthday***

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5. ***Unexplained infertility should be treated by a phased approach according to the female partner's age and duration of infertility.***

6. ***Paternal age should not be included in criteria for acceptance in NHS programmes***.

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7. ***A history of sterilisation in either partner will normally exclude a couple from NHS funding of assisted conception or surgical reversal of male and female sterilisation although there may be exceptional cases where funding is agreed in these cases.***

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8. ***Women with a body mass index of < 19 and > 29 should be referred for advice from a dietician, warned of the potential risks in pregnancy, if appropriate, provided with access to exercise advice and offered psychosocial support. NHS funding of their treatment should be deferred until they demonstrate response to these interventions. Assisted conception may be provided if the BMI is < 36.***

9. ***Smoking should not be an exclusion criterion but patients who smoke should be given advice about its implications. In addition, all smokers should be given the opportunity to be referred to a smoking cessation programme.***

10. ***NHS funding should not be provided to those who have already received the number of NHS funded cycles currently supported by their PCT. NHS funding should be provided to those patients who have had previously self-funded treatment irrespective of the number of cycles providing the clinical circumstances warrant further treatment.***

11. ***Single women and same sex couples should be eligible for up to six cycles of NHS funded donor insemination treatment provided assessment of the Welfare of the Child has been undertaken in line with the Human Fertilisation and Embryology Authority Code of Practice, 2004. After failed donor insemination treatment or in the presence of an indication for IVF allocation of cycles should be on the same basis as for heterosexual couples.***

12. ***Commissioners should ensure that waiting times for NHS referrals for infertility diagnosis and treatment are consistent with national targets for other medical conditions.***

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