



# ASSESSING CHILD WELFARE UNDER THE HUMAN FERTILISATION AND EMBRYOLOGY ACT: THE NEW LAW

*Full report  
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# Executive Summary

## Background and methodology

In 1990 the Human Fertilisation and Embryology (HFE) Act introduced an extensive legal framework for all research and treatment using human embryos in the UK. One short section of this Act placed on assisted conception services an obligation to assess 'the welfare of the child' (WOC) who may be born as a result of treatment pre-conception. This part of the HFE Act became the subject of research and debate in the subsequent years.

Central to the issues raised was the notion that certain patient groups were unfairly denied access to treatment since, by law, clinics were obliged to take into account 'the need for a father' when making welfare assessments. This (and other) criticism of welfare assessments informed a process of legal and regulatory reform, leading to changes in the late 2000s to both statute law and to the Human Fertilisation and Embryology Authority's (HFEA) Code of Practice (COP). The former reform, highly controversially, entailed the replacement of the demand that clinics take into account 'the need for a father' when making welfare assessments with the obligation that they consider 'the need for supportive parenting'.

This study, conducted by staff at the University of Kent and guided by an Advisory Group of experts in the field of assisted conception, sought to provide the first major assessment of welfare of the child (WOC) assessments under the new regulatory framework. The project combined original empirical research with library-based study and received approval from the Kent University Research Ethics Committee, from Oxfordshire REC B NHS Research Ethics Committee and, in line with NHS policy, from relevant Primary Care Trust Research and Development offices.

- We considered successive iterations of the HFEA's COP, to trace the evolution of the welfare assessment, and analysed the published documentation surrounding the 2008 reform to the HFE Act.
- We reviewed previously published studies, mainly from the 1990s, that investigated the process by which clinicians made welfare of the child assessments.
- We conducted face-to-face interviews with (on average) three members of staff with different roles at 20 clinics in the UK (around one quarter of the total number of clinics), generating a set of interviews of a sufficient size to represent reliable, detailed data. The interviews found out about how clinic staff understand and apply the new welfare of the child guidance and, in the light of just under two years' experience of the new system, assessed their views on the advantages and disadvantages of the new procedures.
- Our analysis compared what clinic staff told us about the effect of the new law with the stated aims of law and policy-makers.

## Key findings

1. Changes to the law, and more especially to the HFEA's Code of Practice (COP), constitute a shift to a more liberalised approach to regulation.
2. The HFEA's new 'risk assessment' process is generally perceived by staff to be an improvement on previous procedures, although despite the time spent discussing the welfare of the child (WOC) clause during the reform process, the new law appears to have had a relatively limited impact on clinics' previous practice.
3. The number of prospective patients deemed to raise 'welfare of the child concerns' remains small; very few indeed are subject to further investigation and even fewer are denied treatment.
4. Staff report struggling to work out how to resolve the small number of 'difficult cases' they experience.
5. Staff report variation in, and some concerns about, the role and place of counsellors and counselling in WOC assessments.
6. A low number of formal WOC cases co-exists with widespread concern about the 'welfare of the child'. This concern was expressed in the following three main ways:
  - A *bifurcation* in attitudes towards lesbian patients, and single female patients, was detected by the research; lesbian couples were represented often as 'ideal patients', while concerns were expressed about single women's motivations for having a child, their ability materially to support a child, and the strength of their support networks of family and friends;
  - The patient *group* most frequently discussed as requiring different treatment was donor gamete recipients and the view seemed to prevail that the law requires these patients to be treated differently;
  - A view that the vast majority of patients are 'normal' co-exists with a sense that 'you can never know' or 'you can never prove it'; the spectre of the paedophile shapes perceptions, as a person hardly ever encountered but whose threat nevertheless creates a powerful rationale for pre-emptive action.

## Summary of findings

The following commentary summarises findings first from the library-based part of the research, and second from the interview study.

### 1. The nature of the new regulatory framework

Changes made in the late 2000s to the 'welfare of the child' clause of the HFE Act and to the COP arose at least in part from a perceived need to address 'unfairness' or 'discrimination', most obviously highlighted in relation to those not in heterosexual relationships – lesbian couples and single women.

The introduction by the HFEA from 2007 of a 'risk assessment' process, based around the use of a short list of questions on a form that prospective patients need to answer\*, can be understood as a 'liberalising' measure. In particular the following comprise an important departure from the previous approach:

- Advocacy of a 'light touch' approach, to streamline and simplify the WOC process.
- Guidance that clinics should approach treatment provision with a *presumption in favour of providing treatment to those who request it*, is an important shift. This presumption would operate except in the face of evidence that any child born to an individual or couple (or any existing child of their family) would face a risk of serious medical, physical or psychological harm.
- The directive that: 'in particular, patients should not be unfairly discriminated against on grounds of gender, race, disability, sexual orientation, religious belief or age' (HFEA 2007, Code of Practice 7th Edition, para G.3.3.2).

This 'liberalising' approach from the HFEA was further reinforced after the 2008 legal reforms through COP guidance on how to interpret the phrase 'the need for supportive parenting':

*It is presumed that all prospective parents will be supportive parents, in the absence of any reasonable cause for concern that any child who may be born, or any other child, may be at risk of significant harm or neglect. Where centres have concern as to whether this commitment exists, they may wish to take account of wider family and social networks within which the child will be raised (HFEA 2009, Code of Practice 8th Edition, para 8.11, our emphasis).*

\* *The HFEA risk assessment form asks:*

- 1 Do you have any previous convictions relating to harming children?
- 2 Have any child protection measures been taken regarding your children?
- 3 Is there any serious violence or discord within your family environment?
- 4 Do you have any mental or physical conditions?
- 5 To your knowledge, is your child at increased risk of any transmissible or inherited disorders?
- 6 Do you have any drug or alcohol problems?
- 7 Are there any other aspects of your life or medical history which may pose a risk of serious harm to any child you might have or anything which might impair your ability to care for such a child?

The form asks patients to provide details if 'yes' is answered to any question. Each patient (both partners in a couple, and all parties in a surrogacy arrangement) must sign the form and a second section is used by the clinic to detail any further action taken. The form can be viewed here:

[www.hfea.gov.uk/docs/Welfare\\_of\\_the\\_child\\_Aug\\_2010.pdf](http://www.hfea.gov.uk/docs/Welfare_of_the_child_Aug_2010.pdf)

## 2. Welfare assessment procedures and outcomes

Variations in patient experience (and so the potential for discrimination) have been reduced as clinics generally use common procedures for WOC assessments; one half of the clinics in the study used the HFEA form and almost all of the remainder used a version of the HFEA's form.

However, some forms included questions where distinctions between welfare of the child requirements, NHS funding criteria, and individual clinic protocols, were blurred. For example, some WOC forms asked patients whether, and for how long, they had cohabited with their partner, whether they had criminal convictions (not just for harming children), whether they had any existing children, or whether they smoked. One clinic used a very different form, which asked patients about their alcohol consumption and their use of antidepressants. This was explained as an attempt to reduce the number of patients being assessed as problematic, by establishing protocols for normal levels of consumption.

Most respondents had a favourable opinion of the new simplified process as they found the forms easy to use and less time-consuming.

*I'm not sure it solved any welfare of the child problems, but it solved logistical paperwork.*  
(Person Responsible)

The number of patients at most clinics considered to present concerns following WOC assessment is small (see Table 1).

It appeared that a larger (unquantifiable) number did not access treatment as a result of self-exclusion or the effects of funding restrictions.

*Of course that's incredibly difficult to quantify because they just may never turn up to clinic again and therefore we wouldn't have any evidence at all to try and quantify that figure...But is there an attrition rate along the way? Probably but difficult to quantify.* (Person Responsible)

Those investigated further following risk assessment do not fall into any particular category; no evidence was found of 'group discrimination' based on sexuality or relationship status and 'hard cases' are not of a general kind (see Table 2).

A very small number of treatment refusals result from WOC assessments (see Table 3).

Some respondents commented on finding it hard to resolve 'difficult cases', especially as the general approach was to find ways to be able to treat, and reference was made to a lack of support from other agencies in doing so.

*It does work sometimes and sometimes it becomes a pain when you'll find the GP say, 'I can't provide this', or you find the social services not particularly helpful.* (Person Responsible)

*We tried to get information from various sources and got nothing at all and we ended up having to say, 'Well I'm sorry, but we can't treat you because we can't get the support to say that it's OK.'* (Doctor)

**Table 1**

Number of cases of welfare of the child concern in a year	Number of clinics and clinic size (by annual number of cycles of IVF and ICSI)
0-5	11 clinics (4=< 500 cycles, 5=<1000 cycles and 2=1500-2000 cycles)
5-10	4 clinics (1=<500 cycles, 2=800-1100 cycles, 1=1800 cycles)
10-15	3 clinics (1=400 cycles, 1=600 cycles and 1=730 cycles)
30-60	2 clinics (2=2000-2500 cycles)

**Table 2**

Reasons for concern	Number of clinics reporting cases
Mental illness (including depression)	All
Illness: transmissible or inherited	All
Drugs/alcohol	All
Physical illness or disability	All
Violence in the family environment	10
Convictions for harming children	11

**Table 3**

Number of refusals to treat per year on welfare of the child grounds	Number of clinics
0	7
<1	2
1-2	8
3-4	2
7	1

### **Examples of 'hard cases'**

A male patient in his late twenties disclosed that he had received a conviction for sexually assaulting a young child when he was a teenager. The clinic was willing to treat him and his partner, subject to an 'all-clear' from social services that he no longer posed a risk to children. The clinic was frustrated that social services would not provide a judgement prior to any pregnancy being achieved or a child being born. The couple did not receive treatment.

A male patient had a spent criminal conviction for a violent crime (not related to harming a child), but because it could not be established whether his crime had been triggered by mental illness (there had never been a psychiatric diagnosis) it was felt that treatment could not go ahead.

A clinic refused to treat a woman (rejecting the hospital ethics committee's recommendation that treatment was acceptable) on the grounds that her serious heart problem and other medical complications made fertility treatment and a possible pregnancy unacceptably high-risk, to the extent that her condition was very likely to deteriorate and she could possibly lose her life. The welfare of her existing child was considered to be the overwhelming factor in deciding to deny treatment, but it was also felt that it was unfair for clinic staff to have to provide treatment to a patient with such a poor prognosis.



### 3. New issues in welfare of the child assessments

A relative disappearance of 'group' exclusions by clinics relating to perceptions of desirable family form was apparent; 'single women' or 'lesbians' were not necessarily considered problematic as patient groups by any clinics, never mind *de facto* refused treatment.

*We've become much more comfortable treating both lesbian couples and single women and not putting them through any special hoops...to find out whether we thought they'd be good parents or not. (Person Responsible)*

Compared to previous studies, a notable finding was the bifurcation in attitudes towards lesbian patients, and single female patients. The importance of an approach characterised by 'not discriminating' was more strongly expressed in relation to lesbian couples, who were indeed represented often as 'ideal patients', with 'single women' more commonly discussed as problematic in regards to their motivations for having a child, their ability materially to support a child, and the strength of their support networks of family and friends.

*In reality...lesbian couples are very well thought out often before they come. There still is an awful lot they have to think about, but...they're often a joy to work with because they really do think about the child and managing difference, because they're already managing difference in the fact that their sexuality is different, so they're often very, very well thought out but there's still a lot of stuff we need to discuss. (Counsellor)*

*We're looking at why? Why do it on your own? If you look at Susan Golombok's work, the stuff that comes out is...lesbian women couples do the best parenting. Heterosexual couples do the next best but single women struggle. (Counsellor)*

*[T]hey [single women] have to see the counsellor...she has to look at whether they've got their coping mechanisms...to make sure they've got support mechanisms and things like that. (Nurse)*

Insofar as staff discussed a patient group as treated differently, differentiation was not mainly by merit of the *form of family* the child would grow up in, but was rather by merit of the *nature of the treatment*, namely the use of donor gametes. Some presented counselling as obligatory in this case.

*If any couple are receiving or donating any gametes then we make it a condition of their treatment that they should receive counselling. (Doctor)*

*My understanding is that she [the counsellor] says, 'you really need to tell your children, otherwise you're carrying a lie the rest of your life.' (Doctor)*

Interviewer: *If they'll be using donated gametes, do they have to go to counselling?*

Respondent: *In exactly the same way as a heterosexual couple. There's no discrimination at all. (Doctor)*

Ambiguities were generally associated with the purpose and role of counselling. Respondents reported variation in, and some concerns about the role and place of, counsellors and counselling in WOC assessments.

*This [involvement in WOC assessment] is completely away from my counselling side...you use your counselling skills to elicit information to see what's going on, to see what's not being said, but the patient considers you to be kind of a judge in a sense and, really, to a certain extent you are, because you then determine whether or not something else comes of this matter. (Counsellor)*

In some clinics, there appeared to be a porous boundary between the clinic's role in assessing prospective patients' compliance with Primary Care Trust (PCT) funding criteria and their role in performing the WOC assessment. For example, as noted above, WOC assessment forms sometimes included questions apparently related to funding criteria. However, requirements to screen patients for smoking, Body Mass Index (BMI), relationship stability, age, and existing children, tended to be rationalised by staff on medical or rationing grounds.

- **Relationship stability**

*They are WOC questions because...the recommendation is that we treat people who are in a stable relationship and the ethics committee here said it is considered a stable relationship where two partners live together for at least a year, so that's why we're asking how long they've been together. (Counsellor)*

- **BMI**

*That's a difficult one because I think obesity can be considered a welfare of the child issue if you consider the unborn child, because of the obstetric risk with overweight women. (Embryologist)*

- **Parental age**

Interviewer: *Does the age of either parent ever get discussed as a welfare concern?*  
Respondent: *Yes it does, because we have NHS criteria, we have upper age limits for parents and lower age limits as well, so I think if there was a very big mismatch, we might have some concerns. (Person Responsible)*

- **Smoking**

Respondent: *We've changed it so that now when they come through for a licensed treatment, there's another form that they sign which is a no-smoking agreement...and they actually get told that if we think they're smoking, we can do a smokaliser test on them...And we can stop treatment if we think that's the case...*

Interviewer: *And that's all to do with funding?*

R: *Yes, and also the effect to the child – the unborn child and smoking – I mean we're not dealing with a foetus as such but...they've got to stop at this stage.*

I: *But is it a welfare of the child issue, rather than about the effectiveness of treatment?*

R: *I think it is a mixture.*

I: *And can you see people being refused treatment because of smoking?*

R: *They have been. Yes.*

I: *So not just refused funding, but refused treatment?*

R: *Anybody who has said on their history that they are smoking or anybody that we think is smoking, we just don't call them up. (Nurse)*

#### 4. Perceptions of welfare of the child assessment

There is a strong awareness of an obligation to provide treatment that is non-discriminatory towards patients of particular social groups, and that there must be a presumption that treatment will be provided, including to those about whom 'welfare concerns' are raised, unless these concerns cannot be resolved through further investigation.

*We've never discriminated against same sex and you mustn't. It implies that their relationships are less valid. (Doctor)*

*[W]e don't really refuse many people because we will investigate, we'll get all the evidence and then depending on what it was, we would just try to support them as much as possible and see how we can treat them. (Nurse)*

*[T]here's a presumption to treat...we have to give the patient as much chance as we can to put their sort of side across... (Embryologist)*

At the same time, WOC assessment is viewed as unnecessary and illiberal by very few. Rather, while the new streamlined process is generally welcomed, this is tempered by a view that giving consideration to the 'welfare of the child' is good and necessary (if difficult to achieve) and that whatever the limitations of the formal process, it is intrinsically right for staff to take some responsibility for the future child as a 'third patient'.

*I'd say it [WOC assessment] has the same value as it had 20 years ago; a complete waste of time...the trouble is you immediately discriminate, but...I would like to think that if there was a problem, we would pick that up at consultation... (Person Responsible)*

*I'm a big fan of light regulation and I think it's really only in there [WOC assessment] because it's in the Act...I think it is a serious issue and I think if you did have concerns about welfare of the child, it's absolutely right for it to figure into your decision making but to expect clinics to make an intelligent and a reasonable assessment for that, it's a tricky one. (Person Responsible)*

*The idea behind it [WOC assessment]...is definitely right and proper...Unfortunately, I think many people do think it is a ticking-box exercise. (Doctor)*

*Just because you don't have the same opportunity when it comes to natural conception, it doesn't matter. It doesn't mean that you shouldn't use the opportunity when you can influence what happens. (Doctor)*

*I think we have a responsibility to the couples that are seeking treatment, to any children born as a result of treatment and we also have a responsibility to society as a whole, particularly when we're accessing public funding for patients...if we have concerns then I think it's our responsibility to raise those, just as we would if we saw something...an incident happening in the street. (Person Responsible)*

The need for WOC assessments was often justified in an ambiguous way; most reported that the vast majority of patients were 'normal', but this co-existed with an often overtly expressed sense that 'you can never know' or 'you can never prove it'. The study detected the significance of the spectre of the paedophile, as a person hardly ever encountered but whose threat nevertheless creates a powerful rationale for pre-emptive action.

*Who is going to be honest about having been arrested as a paedophile ten years ago? They're going to hope that they're going to get away with it aren't they? It's very much taking what they say on trust...We can't get everyone to do CRB checks. (Counsellor)*

*I think the obligation for our clinic is to look into the welfare of any child that might be born...you wouldn't want to bring a child into a relationship where the child was at any danger*

*of child abuse or sexual abuse...[A]nything...that sets those alarm bells going would be something that we wouldn't want to risk. (Nurse)*

*We all have to be CRB checked...is it too much to ask the patient to be CRB checked? Is that too far?...I don't have the answer but it's just something that concerned us. (Nurse)*

There was some confusion about the meaning of 'supportive parenting': it was taken by some to mean a new way of referring to 'need for the father', or was interpreted as 'supported parenting'.

*I'm not sure what is 'supportive parenting'...I think a male figure...that a child might relate to...but maybe supportive parenting is not the right word. Maybe it is the right word because I don't know what other term there would be, but it's upbringing of the child, isn't it? (Person Responsible)*

*I must admit I don't use that... but I would certainly use the word 'support': 'Is this child going to be well supported by friends and are you going to be supported by friends and relatives? What would happen if you were ill? Who would then support the child and would help them go to school? What happens if you find you're in an accident and you lost a leg?'...you know – what if, what if, what if? (Doctor)*

# 1: Introduction and background to the study

Infertility is estimated to affect around one in six or seven UK couples (approximately 3.5 million people) and some 35,000 patients make use of in vitro fertilisation (IVF) each year.<sup>1</sup> Since 1990, infertility treatment services have been subject to a highly complex system of regulation: the Human Fertilisation and Embryology (HFE) Act (1990) and accompanying Code of Practice (COP) issued by the Human Fertilisation and Embryology Authority (HFEA). Under this regulatory framework clinicians have a statutory obligation to consider the welfare of the child to be born before accepting any patient for regulated infertility treatment services. This obligation has been the focus of enormous attention and dispute, and in 2008 the 1990 Act was revised following extensive debate. This led to the controversial deletion of the requirement that, in assessing welfare, clinicians must consider the child's 'need for a father'.

The original text of s.13(5) of the 1990 Act provided that:

A woman shall not be provided with [infertility] treatment services unless account has been taken of 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.

This section (as we discuss further below) has been criticised as potentially discriminatory towards single and lesbian women. It also came to appear in recent years to be increasingly out of step with other legal provisions according recognition to same-sex couples.<sup>2</sup> Largely as a result of such concerns, in 2008, s.13(5) was reformed and the requirement that clinicians consider 'the need of that child for a father' was deleted. It was not, however, simply removed from the statute. Rather, it was replaced with the mandate that they must henceforth rather consider the child's need for 'supportive parenting'. This reform of s.13(5) absorbed a very significant proportion of the highly limited time available for discussion of the many amendments made to the 1990 Act, with a range of possible revisions to the section debated at length.<sup>3</sup> This suggests that the precise formulation of the new wording agreed was deemed highly important by Parliamentarians.

Questions of access to treatment are central to patient experience. It is important that regulation in this area is clear and is applied fairly and consistently, yet this imperative sits in obvious tension with the desire to allow for the exercise of clinical discretion in assessing patients. As such, it is unsurprising that s.13(5) provoked significant socio-legal research in the 1990s and it is clear that it remains a pressing issue for new research today, in the light of recent legal changes summarised above. The recent reform raises compelling questions concerning the extent to which perceived problems with the old welfare clause have now been resolved (including whether earlier concerns with discrimination and exclusion have been fully addressed) and the existence of a potential 'regulatory gap' between what the architects of reform intended to achieve in revising the welfare clause and its impact in practice. While this reform might appear to represent significant liberalisation of the law, it continues to mandate the exercise of clinical discretion in deciding whom to treat, clearly thus envisaging the potential for exclusion of some patients as 'unsuitable'. Many (within and without Parliament) wish to retain limits on who can access treatment, with current lively debate focusing on, for example, older women's access to treatment services.

Other problems previously identified with the operation of the welfare assessment also require investigation. These include a lack of common clinical standards and approach; potential problems with clinicians' ability to gather the information necessary to ground equitable judgements; uncertainty as to when to obtain external verification of information provided by patients; whether couples should be interviewed separately or together; the role of GPs, counsellors, ethics committees and other agencies in informing decision-making; and the use of protocols in this regard (Douglas, 1993; Steinberg, 1997; Blyth and Cameron, 1998; Blyth, 1995; Mumford, Corrigan and Hull, 1998;

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<sup>1</sup> <http://www.hfea.gov.uk/infertility-facts.html>. 1.4% - 1.7% of all UK births result from IVF.

<sup>2</sup> Notably: Civil Partnership Act (2004); Adoption and Children Act (2002).

<sup>3</sup> Revision of this one sentence of the statute took over eight of only 80 hours of Parliamentary time available to debate an Act that runs to over 100 pages long.

Lieberman, Matson and Hamer, 1994; Patel and Johnson, 1998; Savas and Treece, 1998; Jackson, 2002). Similar concerns emerged in the HFEA's own (2004) review of the welfare clause.

The welfare of the child provision is a common thread in similar legislation elsewhere in the world, and the 1990 Act continues to be seen as a model for reform programmes elsewhere (Blyth, 2007). As such, a better understanding of the operation of the revised provision in practice should also be a matter of significance and interest for policy-makers and legislators in other countries. In this light, the purpose of the project discussed in this report was to investigate the operation of the welfare assessment following the recent changes to it.

The four questions the study sought to answer were:

1. *Who, if anyone, will s.13(5) henceforth serve to exclude from treatment?*
2. *How do clinics decide who should be treated?*
3. *In the view of clinic staff, have the changes made to the welfare clause solved the problems previously associated with it?*
4. *What is the relationship between law on the books and practice in this area?*

The answers to questions 1, 2, and 3 identified through this study are set out in Section 5. We detail here the responses given by clinic staff in the interviews carried out with them (see Section 4 for an account of methodology). Answers to Question 4 will be set out at a later date, in the light of further deliberation about the relation between law 'on the books' and law 'in practice'.

## 2: The evolution of the legal and policy framework

The origins of the 1990 Act lie in a report produced by a Committee of Inquiry, chaired by Mary (now Baroness) Warnock in 1984. Produced at a time of great anxiety regarding the possibilities opened up by assisted reproductive technologies and what they meant for the 'traditional' family, Warnock had cautioned that:

...many believe that the interests of the child dictate that it should be born into a home where there is a loving, stable, heterosexual relationship and that, therefore, the deliberate creation of a child for a woman who is not a partner in such a relationship is morally wrong... [W]e believe that as a general rule it is better for children to be born into a two-parent family, with both father and mother, although we recognise that it is impossible to predict with any certainty how lasting such a relationship will be. (Warnock 1984, para 2.11).

The text of the 1990 Act did not translate this stricture into a ban on treating anyone other than stable heterosexual couples, although an amendment seeking to criminalise the treatment of unmarried women only narrowly failed in the House of Lords.<sup>4</sup> However, s.13(5)'s requirement that clinicians must consider the need for a father clearly reflected such concerns.

Guidance for how clinics should interpret this provision has been supplied by the Human Fertilisation and Embryology Authority (HFEA) in its regularly updated Code of Practice. The first edition of the Code, published in 1991, advised that where the child would have no legal father:

Centres are required to have regard to the child's need for a father and should pay particular attention to the prospective mother's ability to meet the child's needs throughout his or her childhood, and where appropriate whether there is anyone else within the prospective mother's family and social circle who is willing and able to share the responsibility for meeting those needs and for bringing up, maintaining and caring for the child. (HFEA 1991, para 3.16)

At this time, clinics were obliged to satisfy themselves that the woman's General Practitioner (GP) knew of no reason why she should not be offered treatment (HFEA, 1991, para 3.19); and while the GP should only be approached with her consent, a refusal would be taken into account in considering whether or not to offer treatment. The decision to treat would be made in the light of all available evidence, and treatment might be refused on clinical grounds, on the basis of child welfare, or where there was insufficient information to reach a proper conclusion (HFEA, 1991, para 3.25). Finally, while it is noteworthy that the above advice did not require the production of an appropriate male 'role model' to satisfy the welfare assessment, some patients interpreted it as imposing just such a requirement (eg Harding, 2010, chapter 6).

Subsequent iterations of the Code of Practice served to liberalise the guidance offered on s.13(5). The Sixth Edition (HFEA, 2003) scaled down the specific guidance regarding the assessment of those cases where the child will have no legal father, with the removal of the phrase requiring shared responsibility 'for bringing up, maintaining and caring for the child'. Most significant however were the changes introduced in 2007, following an HFEA consultation, *Tomorrow's Children*, on the operation of the welfare clause (HFEA, 2005). In the consultation, the HFEA committed to developing a 'reasonable, proportionate, fair and practical system' for clinics to conduct welfare assessments (HFEA, 2005).<sup>5</sup> The consultation revealed a lack of any consensus amongst clinicians regarding the value or correct interpretation of the welfare provision and what factors should be taken into account during the assessment process. It also flagged up a number of specific points of concern with the operation of the existing system, including widespread criticism of the requirement that a patient's GP should be contacted as a matter of routine, which was felt to be difficult to implement, unnecessary, and imposing an undue administrative burden. The consultation also revealed a desire on the part of clinics for further guidance on how to interpret the welfare provision and on what steps should be taken to meet their responsibilities under the law.

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<sup>4</sup> Introduced by Lady Saltoun of Abernethy, HL Debs Vol 515 Col 787 (6 Feb 1990).

<sup>5</sup> S Leather (Chair, HFEA): 'Foreword'.

In response, the HFEA introduced a number of changes that were incorporated into the Seventh Edition of the Code of Practice (HFEA, 2007). The most significant of these was the presumption in favour of providing treatment to those who request it, which would operate except in the face of evidence that any child born to an individual or couple (or any existing child of their family) would face a risk of serious medical, physical or psychological harm.

This Seventh Edition of the Code thus retained the requirement that where the child would have no legal father, clinics should consider the prospective mother's ability to meet the child's needs and the ability of other persons willing to share responsibility for them (HFEA, 2007, para G.3.3.3). However, this provision was no longer framed as part of a general assessment of the welfare of the future child but, rather, was included on a list of considerations forming part of a risk assessment of factors that should be checked for likelihood of 'serious physical, psychological or medical harm' to the future child. This represents a subtle but crucial liberalising shift: a clinician who felt, other things being equal, that it would be in a child's best interests to have a father figure might stop short of determining that the absence of the same would be liable to constitute a risk of serious harm.

Second, for the first time, clinics were explicitly directed that '[i]n particular, patients should not be unfairly discriminated against on grounds of gender, race, disability, sexual orientation, religious belief or age' (HFEA, 2007, para G.3.3.2).<sup>6</sup> Finally, clinics were henceforth to contact GPs only where the information gathered from patients gave grounds to suggest that there might be a risk of serious harm to the child, or where the information gathered was incomplete, inconsistent, or deception was suspected (2007, para G.3.4.4). Where a patient refused permission for a GP to be contacted, this should still be taken into account; however, for the first time the Code provides that the refusal should not itself be grounds for refusing treatment (2007, para G.3.4.4). Where further information was collected, treatment should be refused only if the centre concluded that the child to be born or any existing child of the family 'is likely to experience serious physical, psychological or medical harm or where the treatment centre is unable to obtain sufficient further information to conclude that there is no significant risk' (2007, para G.3.4.5). Combined, these changes represented a far more liberal reading of s.13(5) than that envisaged in the first Code of Practice, and a subtle restacking of the decks in favour of the patient's rights to treatment.

The changes to the text of the 1990 Act described above might be seen as fitting closely within, and continuing, this liberalising trend. The 2008 Act was intended, *inter alia*, to provide an opportunity to update the legislation in the light of changing social and familial norms, most notably with respect to the recognition of single and same-sex parents. In the words of the Department of Health, the 1990 Act had been 'framed in terms of heterosexual couples' and should thus be changed better to 'recognise the wider range of people who seek and receive assisted reproduction services in the 21<sup>st</sup> century' (Hinsliff, 2004). As a House of Commons Science and Technology Committee's consideration of the Act further noted, the 'need for a father' provision was akin to a "'fitness for parenting" requirement, historically used to prevent certain "undesirable" groups from reproducing,' and was discriminatory and unjustifiably offensive to many (House of Commons Science & Technology Committee, 2005, paras 93 and 101).

Notwithstanding these views, the revision of the welfare clause sustained considerable interest in Parliament and resulted in numerous votes on its precise (re)wording. First, the House of Lords considered a 'veritable banquet of options'<sup>7</sup> which might be substituted for the 'need for a father' including 'support by a father and a mother';<sup>8</sup> 'supportive parenting and family life';<sup>9</sup> 'supportive parenting and the advantages of having a father and a mother';<sup>10</sup> and 'the advantages of having a father and a mother'.<sup>11</sup> The Government's proposal that 'the need for a father' be replaced by 'the

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<sup>6</sup> The explicit reference to sexual orientation is significant. The 6<sup>th</sup> Edition of the Code stated merely that those seeking treatment 'are entitled to a fair assessment', which should be conducted 'with skill and care' and due regard 'to the wishes and sensitivities of all involved' (HFEA, 2003, para 3.12).

<sup>7</sup> Per Lord Warner, HL Debs, Vol 698, Col 71 (21 January 2008).

<sup>8</sup> Amendment 108A, tabled by Baronesses Deech and O'Caithan and Lord Lloyd of Berwick.

<sup>9</sup> Amendment 108B, tabled by Lord Northbourne, Baroness Butler-Sloss and the Earl of Listowel.

<sup>10</sup> Amendment 108C, also tabled by Lord Northbourne, Baroness Butler-Sloss and the Earl of Listowel.

<sup>11</sup> Amendment 101A, tabled by Baroness Deech and Baroness Butler-Sloss.



need for supportive parenting' was finally agreed.<sup>12</sup> In the House of Commons, attempts at amendment continued with a range of options aiming to reinsert explicit mention of a father. Suggestions included the 'need for a father and a mother'<sup>13</sup> and the 'need for supportive parenting and a father or male role model.'<sup>14</sup> In the end, however, these further amendments were all defeated and the need for 'supportive parenting' survived into the final text of the legislation.

As well as showing a clear lack of consensus on how the law should be reformed, the debates also clearly reveal the significant gulf in how Parliamentarians interpreted the term 'supportive parenting', highlighting the extent to which the provision operates as a compromise measure, designed to respond to continued anxieties surrounding assisted reproductive technologies and those who seek to avail of them, most significantly in relation to the role of men and fatherhood (see generally, McCandless and Sheldon, 2010). As noted above, the amount of time spent debating this issue would also suggest that Parliament considered the precise wording of this provision to be a matter of great practical significance.

The current Code of Practice, which takes account of the changes introduced in the 2008 Act, serves to build on and extends the liberal reading given to the welfare clause in the Seventh Edition. The Code's definition of 'supportive parenting' is as follows:

Supportive parenting is a commitment to the health, well-being and development of the child. It is presumed that all prospective parents will be supportive parents, in the absence of any reasonable cause for concern that any child who may be born, or any other child, may be at risk of significant harm or neglect. Where centres have concern as to whether this commitment exists, they may wish to take account of wider family and social networks within which the child will be raised. (HFEA, 2009, para 8.11)

Significantly, the guidance given explicitly places the burden of proof on those who would seek to refuse a woman access to treatment: those seeking to make use of assisted reproduction are to be presumed suitable parents unless, following a risk assessment, there are grounds for suspecting that the child to be born will be at risk of significant harm or neglect (HFEA, 2009, para 8.3). As part of this analysis, clinics are directly to consider a relatively narrow range of factors that are 'likely to cause a risk of significant harm or neglect to any child who may be born or to any existing child of the family.' The list of factors to be considered includes, for example, past or current circumstances that may lead to any child mentioned above experiencing serious physical or psychological harm or neglect; past or current circumstances that are likely to lead to an inability to care throughout childhood for any child who may be born; mental or physical conditions; and drug or alcohol abuse.

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<sup>12</sup> Amendment 108, tabled by Lord Darzi on behalf of the Government.

<sup>13</sup> Amendment 56, tabled by Iain Duncan Smith, David Taylor, Claire Curtis-Thomas, Johan Gummer, Michael Ancram and Geraldine Smith.

<sup>14</sup> Amendment 58, tabled by Mark Simmonds and Andrew Lansley.

### 3: Studying welfare assessments 1990 to 2009

The legal and policy changes described above evolved alongside a set of arguments and research findings published in the academic literature, and were influenced by them (Blyth, Burr and Farrand, 2008). We now turn to consider this literature, which overall has two main features. First it provides an empirical assessment of how welfare assessments were made by clinics, and second it offers legal and ethical analysis of s13.5 and the reforms to it. Underlying this body of work as whole, however, is an acknowledgment that the 'welfare clause' from the outset has been contentious and has generated contest about its purpose and ethical acceptability.

The seminal reference point is the study by Douglas (1992, 1993), which appears to have been the largest study conducted hitherto. Douglas surveyed clinics offering assisted reproduction treatment about their welfare assessments procedures, and also 'attempted to find out from some consumers ... what their experiences had been in respect of having their parenting ability and motivation scrutinised' (1993, p60). In this research, questionnaires were sent to 124 centres, which were identified as offering assisted reproduction treatment (defined in this study as artificial insemination, IVF, gamete intrafallopian transfer [GIFT] and related techniques), and 'the consumer study' involved analysis of questionnaire returns from 200 women. Key findings were as follows:

**1. Most centres responding continued after 1990 to do what they had always done in deciding whom to treat.** Douglas argued that, 'Quite simply, the Act and Code of Practice...has not revolutionised attitudes or practices of those working in this field, at least in relation to access to treatment, and at least in the none months or so following the implementation of the Act...under one fifth...of the survey clinics has altered their criteria for accepting patients...and nearly as many of these had narrowed their criteria as had widened them' (1993, p62).

**2. Centres 'weeded out patients' regarded as unsuitable at an early stage, often before a consultation took place.** The author argued that, 'Although no type of person is ruled out by the legislation from being eligible for treatment, in practice clinics appear to have developed their own guidelines, protocols or rules of thumb to weed out certain categories from consideration' (1993, p62).

In regard to the issue of which individuals or groups of people clinics would not treat on child welfare grounds, Douglas found very few clinics reported 'that they excluded no-one on principle', and she therefore concluded that it seemed clear that 'nearly all clinics did decide in advance whom they would begin to consider for treatment' (1993, p63). The details provided indicated that it was unusual for clinics not to treat unmarried couples, but it was the case that, both before after the 1990 Act, a lot of clinics (the study indicated around one half) would not treat single women. Douglas found that, in contrast, there had been a shift in practice comparing before and after the Act for surrogacy:

Nearly three-quarters of clinics said they would not take part in surrogacy arrangements prior to the Act, but this was the category where there was most willingness to change...the kind of surrogacy being facilitated was 'full surrogacy'.... This suggests that doctors may see the surrogate's role as less significant or problematical where she is not the genetic mother. (1993, p63)

This study also found that the age of the woman was a criterion used to exclude almost half of the centres, since they imposed a maximum age limit on accepting a woman for treatment (although it is noted this ranged widely – from 36 to 50). Emphasis was also placed by this author on the interplay between funding for treatment and welfare of the child assessments:

Clearly funding is a problem in the NHS and there may be a wish to channel available treatments to those deemed most in need...value judgements play a part in rationing healthcare resources. It seems that patients who do not fit the standard model of a heterosexual couple in a stable relationship may be regarded as less justified and less well-qualified to be parents and so not entitled to take up scarce resources...Similarly women over

a certain age may be excluded not just because they are less likely to succeed in treatment but also because it may be felt to be inappropriate to create 'elderly' parents...Finally the fact that even the majority of private clinics responding said that they imposed restrictions on whom they would treat suggests that a view of social suitability may be taken even where there are no resource constraints operating. (1993, p64)

**3. Centres appeared to make little effort to assess, on an *individual* basis, the likelihood of the child's welfare being at risk if the patient were treated.** The responses to questions asked about the process of making a welfare of the child assessment, argued Douglas, revealed the following.

The central finding was that centres appeared to rely on 'a very narrow range of informants' when deciding whether to treat and 'and asked 'very few questions of their patients along the lines envisaged by the Code of Practice'. Hence, it emerged that virtually all clinics asked the patient and her partner, but Douglas observed that, 'it cannot be assumed the complete candour is always offered...' and that, 'nor may it be wise to do what appeared still to be very common – which was to see the couple together only rather than separately as well as recommended by the HFEA...One partner may be going along with what the other wants and unwilling to express doubts about the treatment'. In addition, it was found that 'most centres also obtained information from the GP', but Douglas suggests this may be problematic also, as 'Clinicians may feel that the GP will know far more about the patient to advise on their suitability...but this seems optimistic' (1993, p65-66).

Douglas also commented on findings about counselling, noting that: 'Just over a third of the clinics routinely used the counsellor as a source of information in the assessment'. This, she argued, 'fulfils the HFEA recommendations but is problematical. The Code appears to assume that counselling can be distinguished from assessment but patients do not always see it like this...' (1993, p66). She also noted that, 'The Code advises that if possible where there is cause for concern further enquiries should be made of any relevant individual authority of agency. The survey found that this was done relatively infrequently. Fewer than one fifth of private clinics had ever used social services...although about 40 per cent of NHS clinics had done so in exceptional cases'. In regard to assessments, her other observation was that, 'Not only was very little...information apparently collected by clinics on their patients but the decision to treat in two-thirds of those responding...rested with the medical person in charge of the case. About a fifth of centres said the decision was taken by the team, and only 4 out of 66 said that the ethics committee decided'. (1993, p66-67)

Overall, this study found that, once a prospective parent has been accepted by a clinic for a consultation appointment, 'it was unlikely that they would be pestered with questions or investigations about their background or suitability to care for children'. The general conclusion drawn by Douglas was that:

On the basis of this study s13(5) does not appear to have forced or even encouraged clinics to alter their approach to whom they will treat. It permits clinicians to decline to take on those people to whom they object without requiring any investigation or even much justification for their decision. It has not introduced a system of scrutiny of prospective parents which would purport to identify possible risk to children. Clinics in the survey remained dependent upon the patients and their GPs for most of the rather limited information that they gleaned about them. It may be concluded therefore that decisions are taken on the basis of viewing a person as infertile or not, rather than childless, and as of appropriate status or not, rather than as individually capable of safeguarding a child's welfare. (1993 p68)

Her case, on the basis of these findings, was that the HFEA should do much more to ensure clinics develop thorough, meaningful procedures for Welfare of the Child assessments. She argued that the onus should be placed on the HFEA to:

...provide additional, more categorical and detailed guidance to clinics on what to take into account when considering the prospective child's welfare...the task is surely for them to decide, if s13(5) is to be no more than lip-service provision, designed to reassure the public that clinics are taking their job seriously, of which there was little doubt anyway, and which allows clinics to follow stereotyped opinions about suitability to parents, or whether it is to be

used as a positive means of asserting exactly whom, as a society, we consider eligible for our help in becoming parents. (1993, p71)

Since the publication of this, study, the issues identified by Douglas were taken forward in various ways. As outlined in the previous section, the subsequent years saw ongoing discussion about the problem of 'stereotyped opinions' (eventually resolved formally through the removal of 'the need for a father' as part of the wording of s13(5)), and additionally the development of both important debate about the desirability and plausibility of assessing 'the welfare of the child' before conception (see especially Jackson 2002, 2008) and protracted attempts to develop more meaningful guidance for clinics on welfare assessments on the part of the HFEA. With regard to empirical work, the areas raised by Douglas (exclusions of groups of prospective patients; procedures for making welfare assessments compared to COP guidance; the use of counsellors for making assessments) have all been revisited, and some interesting changes over the 1990s identified. In the 1990s, empirical and analytical work most relevant to this study was completed by Blyth (1995) and Savas and Treece (1998).

The former study, described by the author as 'exploratory', used semi-structured interviews with staff in six treatment centres and with five HFEA inspectors. Interviewees at clinics included two clinicians, three counsellors, two nurse managers and one centre administrator. One area of this study focused on finding out about 'refusal to treat', with the author noting that the welfare of the child provision can be used as justification for limiting provision in three ways: first, to prohibit particular services, eg surrogacy; second, to exclude certain groups from treatment (for example on the basis of age, disability, marital status, or sexuality); and third, to withhold treatment in certain circumstances (eg previous convictions or suspicion of risk of harm to a child that may be born from treatment).

On these areas, overall the study detected a rather different situation to that described by Douglas (1993). Notably, that author argued they found a 'less discriminatory approach by centres. Only one imposed such an embargo [exclusion prior to consultation], an NHS-funded centre which did not offer treatment to either single women or lesbians. Each of the other centres indicated they would treat these groups...' (Blyth 1995, p423). With regard to age, it was found that:

Four centres...stated there was no 'blanket' upper age limit...and that each case would be judged on its own merits, although all had a *de facto* limit...The two centres with upper age limits (36 and 50) stated this was imposed on the likelihood of the success of treatment...rather than on any possible relationship between the welfare of the child and 'older' parents'. (1995, p424.)

Further, 'None of the centres imposed blanket exclusions on health grounds [disability]...', and while only one of the Centres did surrogacy, this 'was not considered to pose special welfare problems concerning the child' (1995, p424). Rather than 'blanket' or 'group based' restrictions, Blyth found instead that:

...staff identified grounds which might justify refusal to offer treatment in *specific instances* such as convictions for child abuse, the removal of a child...histories of drug or alcohol misuse, or psychiatric disorder, although none had been faced with such issues. And whilst two centres specifically asked prospective patients for information about criminal convictions, no further checks were made to ascertain accuracy of the information given. (1995, p424)

Blyth also sought to investigate the process by which clinics made welfare assessments, again noting Douglas' opinion that clinics did not do so rigorously. On this area, Blyth stated:

[T]he present study identifies considerable variations in practice between centres and highlights the importance to the information-gathering and assessment process of 1. the range of sources of information; 2. the range of staff involved...; and 3. centres' arrangements for dealing with 'cause for concern'. (1995, p425)

It was found, in common with Douglas (1993), that the prime source of information was patients themselves, from whom staff obtained medical and social histories, and also that HFEA

recommendations on seeing the woman and partner together were often not followed. Routinely, centres also sought information from the patient's GP and from any other doctor known to be providing treatment. In the study, notes Blyth, no centre had extensive experience of seeking further information from external agencies.

Blyth also found, in common with Lieberman, Matson and Hamer (1994) (see below) that:

Practically, unless the attention of the doctor, nurses or counsellor is alerted or drawn to a particular set of circumstances by either the letter of referral, the couple's behaviour or attitude during counselling or treatment, or their medical or social history, the ability of the centre to comply with this regulation [welfare of the child] is severely curtailed. (1995, p425)

In other words, attention is drawn to the practical difficulties of envisaging exactly how (if it were considered desirable to do so) a clinic might go about making genuinely thorough assessments. In this regard, Blyth notes that opinions among respondents varied about the adequacy of information-gathering, it being seen as 'skimpy' by social work standards, but also that staff considered that, 'The test of patients' commitment and suitability was often measured by the self-evident effort they were prepared to make to achieve parenthood....' (1995, p425).

Blyth also drew further attention to the role of counsellors in welfare of the child assessments, noting that, 'The role of counsellors in assessment though appears ambiguous and controversial', and that 'assessment fits uneasily with the concept of non-directional counselling'. This author states that his study:

[P]rovided evidence of referral to the counsellor for assessment masquerading as referral for counselling...There was also evidence of the imposition of 'mandatory counselling' for certain groups of patients...A further area of tension for counsellors is recognition of their dependence, as well as that of other centre staff, on patients' veracity, and limited opportunities for checking information provided. (1995, p427)

In regard to counselling, this study also raised the issue (not commented upon by Douglas) of donated gametes, specifically the procedures in place for counselling donors (rather than recipients). Concluding observations about perceptions of the regulations were that:

Respondents' perceptions of the effect of the Act...were mixed...although the weight of responses from centre staff tended to suggest that it had exercised minimal impact...Several staff claimed the Act had made no difference to practice...Other respondents – including all the inspectors – thought that the welfare of the child was 'much more upfront now than a year ago'...The limitations of the inspection process were, nevertheless, apparent...There is evidence that inspection is not merely 'rubber stamping'...However evidence of ambiguity from this study reinforces accounts of the inspection process [from others]. (1995, p 430)

Savas and Treece (1998) sought through their study, published three years after Blyth's, to investigate the wider issue of 'how clinics interpret the [HFEA] guidelines, and...examine the question of whether the existing guidelines should be tightened to remove some of the inherent ambiguities' (1998, p243). This study, which sought to collect and analyse responses to a questionnaire sent to all registered clinics (using a mixture of open and closed questions), focused in large part, however, on finding out about welfare of the child assessments (a 53 per cent response rate was obtained). The authors posed the focus for their research as follows:

If it is to be accepted that assisted conception services should be regulated in a way naturally occurring pregnancies are not, an obvious starting point in any investigation into decision-making in this area has to be the approach adopted by clinics when dealing with the dilemma of to whom are they prepared to offer services, and conversely, which prospective parent(s) they would refuse to help. This process forces providers of fertility services into making decisions as to who will make the 'better' parents by implication. (Savas and Treece, 1998, p246)

As noted previously, some have set out substantive objections to the meaningfulness and moral integrity of the statutory demand for 'welfare of the child' assessments prior to conception (Jackson, 2002, 2008). Savas and Treece do not appear to share this view; they conclude from the responses to the questionnaire that, 'The fact that the majority of the respondents consider the welfare of any potential child to be of prime importance is a reflection of the central importance placed on the concept by the 1990 Act and should be welcomed' (1998, p254). Their interest, rather, is in how fairly, objectively and consistently clinics make assessments, and they conclude their study by making suggestions as to how the process could be improved. The main areas of interest that they consider emerged from their study in regard to welfare of the child assessments are as follows.

First they note that ('Perhaps unsurprisingly', given the demands of the HFEA), the main criterion respondents took into account when making 'ethical decisions' about treating a prospective parent was the welfare of the child (69 per cent). They note this compares with 22 per cent for 'the welfare of the patient' and 13 per cent for 'the stability of the patient's relationship', 'welfare of existing children', and 'the agreement of the treatment team'. Another question gave respondents the opportunity to weight factors on a scale of 1-6, to indicate the relative importance of factors they take into account, when making decisions about whom to treat. In this case, too, 'the welfare of the child' was given most significance, as it was most commonly viewed to be the most important factor. Respondents rated the 'welfare of the patient' and 'stability of relationship' as less important, and fewer again rated 'a parent of either sex', the patient's age, and the age of the patient's partner as very important. There were considerable variations between responses, leading the authors to observe, 'there is considerable scope for interpretation of some of the guidelines by individual clinics. This in turn leads to the suspicion that clinics are not adopting a consistent approach' (Savas and Treece 1998, p249).

Respondents were also asked about what treatment decision their clinic would make in what might be construed 'morally problematic' cases. These were: childless single woman; single woman with children by another partner; homosexual couple; woman over 40; woman over 50; widow requiring AIH [Artificial Insemination by Husband]; woman who is HIV+; woman who intends to act as a surrogate mother; woman who have been previously voluntarily sterilised. Respondents could answer 'Yes', 'No', 'Possibly', 'Probably' or 'No answer' when asked were they would treat such prospective parents. The most consensual response was for 'Woman over 50', where no-one replied 'Yes' and 11 per cent indicated they would consider treating. The highest proportions of 'Yes' responses (over half in both cases) were for 'woman over 40' and 'woman who had been previously sterilised'. This would seem to suggest a clear 'bright line' in regard to age, where 50 appeared as the 'cut off' of acceptability for most clinics.

This finding on age seems to contrast rather with Blyth (1995), as do Savas and Treece's findings on cases relevant to 'the need for a father'. These authors draw particular attention to the results for single woman and 'homosexual couples', on the grounds that 13(5), given its reference to 'the need for a father' would appear to be clearly representing such prospective parents as suspect. They note, in this light, that 'it is significant that almost 44% of the sample failed to rule out treatment' of a childless single woman, and a similar percentage 'failed to rule out treating a homosexual couple (generally interpreted by the respondents as referring to a lesbian relationships)'. They argue that these results should be viewed as 'anomalous' as, 'when examining the best interests of the child, and the provision of a stable environment, two parents (of whatever sex) are arguably better able to provide these requirements than one' (1998, p251). The percentages indicating that they would not treat single women or lesbian couples (over 50 per cent in both cases) appear high, however, compared with findings from Blyth (1995). Other results highlighted by Savas and Treece were that 60 per cent of respondents ruled out treating an HIV+ woman, with only two clinics answering 'Yes', and in contrast a relatively low proportion (25 per cent) ruled out treatment of a potential surrogate mother.

The last area the survey investigated was how risk assessments were made, as required by the HFEA's Code of Practice. The authors note that one respondent commented that it was fundamentally unfair to require people to undergo this process, as it is not an 'obstacle' facing fertile people. The methods respondents indicated were used were: a form filled in by the patient; a reference to the patient's GP (after obtaining the patient's permission); a decision made by the treatment team, after independent counselling of the patient; queries sent to outside agencies (social workers or social services); and each case decided on its own merits.

The authors indicate their concerns about this picture of risk assessment centre on its lack of 'objectivity'. They state:

It is submitted that, firstly, any form of self-assessment by the patient will tend to lack objectivity, given the desire for a child is often over-riding. Secondly, although the general practitioner will have records of his or her patient's medical history and may have some knowledge of the patient gleaned during brief consultations in surgery time, it is highly unlikely the doctor will be able to give a skilled assessment of family functioning or parenting skills. (Savas and Treece 1998, p254)

The other study published the same year was authored by Patel and Johnson (1998), which reported a survey of 71 clinics in the UK offering in vitro fertilisation (IVF) treatment. In this research, clinics were asked simply to provide their written protocols used for assessment of the welfare of the child. A total of 44 (62 per cent) responded. Of these, five (12 per cent) did not have operational protocols, seven (16 per cent) declined to provide their protocols, and 32 (73 per cent) provided *information* used in the survey. The information was in the form of a *protocol*, however, for only 16 of these clinics. The remaining clinics submitted as their 'protocols' letters to GPs, patient information, patient questionnaires and/or a copy of their policy on the assessment of child welfare.

From the submitted material, the authors determined that 94 per cent of clinics seek information on aspects of child welfare, 78 per cent have a procedure for making further enquiries where there is any cause for concern, 44 per cent include counselling opportunities explicitly in protocols, 30-38 per cent of clinics see a full medical and social history from each prospective parent as part of the child welfare assessment, 16 per cent include explicit consideration of the impact of multiple births on the welfare of the child, and 3 per cent include consideration of the issue of disclosure of the mode of conception of the child on its welfare. Most clinics, it was found, did not have clearly defined procedures on how to reach a decision to treat. Eight clinics (25 per cent) made explicit in their protocols any exclusion criteria.

The other study of some relevance from the 1990s was by Lieberman, Matson and Hamer (1994). This did not directly research welfare of the child assessments, but rather comprised, 'A confidential and anonymous survey...to assess the opinions of 'responsible persons' in every licensed unit as to the initial benefit of the [HFE] Act and its administration by the Authority since its inception in 1990'. To find out about this, questionnaires were sent to the 'Person Responsible' (PR) in every licensed unit, replies were received from 99 of the 113 such units, and of these 90 forms contained sufficient information for analysis. One question asked, 'Do you feel that the Code of Practice (as revised) is generally working well? If no, please explain which parts should be further revised', and it was found that:

The majority (78%) were satisfied although *ambiguities relating to the need to take into account the welfare of any child born or the existing children gave cause for concern*. Rigid application of the confidentiality clauses, the consent form for communication with the general practitioners and confusion about interpretation of the Code, even by members of inspection teams, were commented upon. *The emphasis on counselling was thought to be excessive*. (Lieberman, Matson and Hamer, 1994, p1779-80, our emphasis).

The conclusion drawn by the authors with regard to welfare assessments was that:

Practically, unless the attention of the doctors, nurses or counsellors is alerted or drawn to a particular set of circumstances by either the letter of referral the couple's behaviour or attitude during counselling and treatment, of their medical or social history, the ability of the centre to comply with this regulation is severely curtailed. It is apparent that the Authority's insistence on counselling particularly at Annual Inspections is perceived to be disproportionate compared by laboratory and clinical matters. (1994, p1781)

At the end of the 1990s, two useful summaries of the main themes to emerge from the prior research were published in *Human Reproduction* by Blyth and Cameron (1998) and Mumford, Corrigan and Hull (1998). In the first, Blyth and Cameron argue:

In practice, provisions made for the welfare of the child may be ineffective and permit less legitimate and discriminatory activities, such as the exclusion of certain social groups or the prohibition of particular treatments which are legitimized in UK law. Nevertheless, Blyth (1996) [actually 1995] concluded that licensed centres 'may be less ready than previously thought to use the welfare of the child as a convenient, if thinly disguised, rationale for refusing to provide certain services or treat certain people'. This discord seems likely to continue (Blyth and Cameron, 1998, p2341).

They also note that,

[R]ecent research has shown the welfare of the child to be a slippery concept. The welfare of the child test lies within the remit of each individual licensed treatment centre, who draw up their own individual protocols regarding the welfare of the child. Clinicians managing licensed treatment centres have pressing concerns about their ability to gather the information required to reach an equitable judgement of 'risk'...Baroness Warnock noted recently that regulation may rest on 'guessing about the good of the child'. This lack of a collective approach and a common standard detracts from the effectiveness of the welfare of the child test. (Blyth and Cameron, 1998, p2341)

Mumford, Corrigan and Hull in 1998 raised broadly speaking similar issues and concerns. One additional point to which they drew attention was that:

Sometimes counsellors are left in the invidious position of assessing patients while purporting to counsel them. Much can probably be gleaned about a couple by astute staff in the course of several meetings, and most of those requesting assisted conception are probably very satisfactory potential parents. Nevertheless it might buttress the present legal requirements and the ability of centres to comply with them if there were some more standardized means of identifying problem cases. One possible method might be the introduction of assessment procedure, along the lines of that used in adoption, but with the presumption in favour of allowing the treatment to go ahead as long as there was no evidence of anything on the list of contra-indications. (Mumford, Corrigan and Hull, 1998, p2354)

Writing in the late 2000s, in the context of the publication of the HFEA's revised guidance to fertility treatment based on *Tomorrow's Children*, and a year before the HFE Act was revised, Blyth, Burr and Farrand (2008) provided a further summary of the issues that had been relevant in generating this HFEA review. For example, they drew attention to the perception that:

13(5) was being used by at least some clinics as a means of discriminating against women seeking assisted conception services, primarily on the grounds of their marital status, sexual orientation, and age; however, variable approaches towards the welfare of the child meant that women denied a service in one clinic might well find another clinic prepared to offer them treatment. (Blyth, Burr and Farrand, 2008, p31-32)

They further note comment had been passed about the legitimacy of disqualification on child welfare grounds of 'advanced maternal age; a life-threatening illness; a significant learning or physical disability; a serious mental health condition; alcohol or drug misuse, conviction for sexual or violent crime, or child protection measures taken regarding an existing child or children' (1998, p32). They also note, however, that it does appear from empirical assessment that 'barriers for women without a male partner are diminishing' (although there are still barriers to access). People are 'rarely turned down', they state, and the main reasons for this happening appeared to be 'medical', (specifically, because the person requesting services had a serious health condition, mental illness or alcohol or drug misuse) or 'social' (a couple requesting services not living together).

Further important points made by Blyth, Burr and Farrand, citing evidence given to meetings of the Parliamentary Science and Technology Committee in 2004 and 2005 (held as a contribution to discussion of upcoming reform of the statute) are that, first, a more recently made argument *in favour of rigorous welfare* assessments has concerned treatment using donor gametes. They note that the Donor Conception Network 'has advocated for donor procedures to be restricted to people giving an



advance undertaking that they would tell their child about his or her conception' (2008, p32). Second, they also note that some medical organisations have made *forceful criticisms* of welfare of the child assessments altogether. Hence they note that:

[R]epresentatives from the British Fertility Society and the Royal College of Obstetricians and Gynaecologists considered the child welfare requirement to be redundant, although the Britain Medical Association proposed a welfare assessment focusing on identifying 'those few cases in which a future child is at clear risk of serious harm, rather than seeking to restrict treatment to couples who conform to some traditional notion of an 'ideal family set up'. (2008, p33)

They also note that the Science and Technology Select Committee advocated 'a radical position' that would 'remove the clinic's responsibility to take into account any child welfare considerations before offering a service, but would merely require them to alert social services if they became concerned for the welfare of any child born as a result of treatment they were providing' (2008, p33).

In the light of all of this, after a process of legal reform that purported to take into account these various issues, and after around two years of the operation of the new s13.5 and associated guidance from the HFEA, this study sought to revisit the issues raised above. It aimed to find out if the new regulations have effectively assuaged previous concerns by providing clarity and certainty for clinicians while at the same time ensuring the approach taken is not discriminatory, investigating the following areas:

- The procedures used to make welfare assessments, including use of HFEA materials;
- Do clinics have protocols and if so what do they say?
- Do clinic staff feel confident about assessing risk as it is now defined by the HFEA?
- How do they go about assessing risk?
- What risks do they feel are important? If so what are they and why?
- Are particular treatments viewed differently with regard to risk?
- The uniformity across clinics of procedures used carry out welfare assessments, in general, and where further investigations of individuals are deemed warranted in the grounds they may present a child welfare risk;
- The place of counsellors/counselling in making welfare assessments;
- The degree of importance attached to 'the welfare of the child' as a reason to treat or not treat, and whether it is considered a meaningful concept;
- What 'the welfare of the child' is taken to mean;
- To what extent requests for treatment from lesbian women or single women are seen as problematic, given that s13.5 no longer states that 'the need for a father' should be taken into consideration;
- What other issues or factors are considered 'welfare' concerns? (Including issues that have emerged recently or which have become particular foci for debate about provision of assisted conception treatments: a patient's transgender status; cases where one parent is serving a long-term prison sentence; clinical obesity; and where those seeking treatment together are not living together in a sexual/intimate relationship,<sup>15</sup> or are in other forms of relationship that might raise concerns (eg polygamy: see HFEA 2004);
- The extent to which child welfare concerns may be triggered by requests for particular kinds of treatment (eg surrogacy, treatment using donated gametes, and intra-familial gamete donation).

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<sup>15</sup> The 2008 Act imposes no requirement that the two individuals be partners, although the Code of Practice continues to use the term 'partner' to refer to the second parent.

## 4: Methodology

The project combined original empirical research with library-based study. The latter drew both on existing academic commentary on the legislation and reform process, including existing empirical work on the welfare clause. We considered successive iterations of the HFEA Code of Practice, in order to trace the evolution in guidance regarding the welfare assessment and drew extensively on the published documentation surrounding the introduction of the 2008 Act (particularly Department of Health, 2005, 2006, 2007; House of Commons Science & Technology Committee, 2005; House of Lords/House of Commons, 2007a, 2007b; and Parliamentary debates). The key findings of this aspect of our work have already been summarised in sections 2 and 3, above.

The remainder of this report focuses on our empirical research, and this involved the collection of data that sought, first, to provide a detailed account of how clinic staff understand and apply the new welfare of the child guidance and, second, in the light of just under two years' experience of the new system, to track their views on the advantages and disadvantages of the new procedures. While some previous research (eg Douglas, 1993) drew on interviews with service users, this study focused exclusively on the views of clinic staff. This has, we hope, laid the groundwork for the design of subsequent work to explore service users' experiences, whilst giving the new system longer to 'bed in' (thus providing a sufficiently large patient group in whom the possible variations in experience of the new procedures might be researched).

Some previous studies (Douglas, 1993; Lieberman, Matson and Hamer, 1994; Savas and Treece, 1998) have used the approach of sending postal questionnaires to a sample inclusive of all UK clinics, but not only has the use of postal questionnaires tended to produce variable response rates – from 90/113 (Lieberman, Matson and Hamer, 1994) to 67/124 (Douglas, 1993) – the methodology was also judged to carry time and cost implications incommensurate with this study's staffing and budgetary resources. The studies referred to here were carried out during the 1990s, when the NHS requirements for ethical and Research and Development (R&D) approval were less extensive. Carrying out such a study in 2011/12 would require securing approval from the relevant Primary Care Trust (PCT) and the Research and Development office responsible for each clinic. It was judged that to gain such approval for all UK licensed clinics would be impossible, given time and financial constraints. Our subsequent experience, discussed below, of just how time-consuming the process of gaining PCT approval for access to clinics and staff can be, has indicated that this decision was correct.

The target sample size was 20 clinics, which represents approximately one quarter of the 77 clinics licensed in the UK to carry out IVF treatment. Clinics providing only intrauterine insemination (IUI) or gamete storage were excluded on the basis that, although these treatments are now licensed, this was not the case before 2009, and they therefore have limited experience of operating within the HFEA guidelines concerning welfare of the child. Our methodology was designed primarily to take account of the inherent difficulties involved in seeking to generate comprehensive and detailed information from busy medical professionals. Recruiting a smaller sample, with the help of Advisory Group members with strong contacts within the sector, was judged to be both an efficient use of project time and a way of avoiding harassing clinic staff with excessive paperwork. Concentrating data collection in a smaller number of clinics enabled us to spend more time gathering face-to-face, in-depth data from a range of professionals, rather than responses from one informant. Although face-to-face interviews obviously require a time commitment from clinic staff, they could be carried out during a one-off visit, at a time convenient to clinic staff, and could be conducted as a conversation, without the need for advance preparation by staff. Many respondents reported that they found taking part in the study useful as it allowed them time to reflect on their practice and consider the broader context of their own clinic's procedures. The intention was to gather data that could be used to quantify and compare practice across a representative sample of UK clinics, but also to explore in some depth the understandings of, and meanings attached to, the welfare of the child assessment by professionals in their everyday practice.

The decision to interview multiple staff members at each clinic was the result of the advice from members of the Advisory Group established for this project that members of staff other than clinicians play an important role in the welfare of the child assessment. On the advice of Advisory Group members we therefore aimed at the outset to interview the lead clinician, also usually the 'person

responsible' (PR) (it is a statutory requirement that each clinic has such a person), and two other members of staff – for example, nurses and counsellors who also see patients and may have different experiences of the welfare of the child assessment. Thus in planning the project, our aim was to interview on average three staff members at each of the 20 clinics. Members of our Advisory Group subsequently suggested that in some clinics, Embryologists may also have involvement in the welfare of the child assessment and would therefore be worth interviewing. It was then decided to include Embryologists at clinics where they played a role in welfare of the child decision-making.

Visiting clinics in person allowed for an ethnographic dimension to the fieldwork that would have been impossible with a postal questionnaire. It meant that the research took on a more sensitive character, as staff could respond to the questions asked in the interview with references to the clinic surroundings and people (both staff and patients) within it, and were sometimes able to recommend for interview members of staff who had not been formally recruited for interview in advance, but who, through the course of the research visit, were described as having an important role in the welfare of the child assessment. A diversity of views and experiences is reflected in the data that would not have been possible, had the research questions been addressed to one key informant. The resulting data is more nuanced and contains a more complicated, less 'official' picture of the welfare of the child assessment than it would if the sole respondent had been the individual formally responsible for welfare of the child procedures, supplying written answers to a postal questionnaire. The disadvantages of taking such a qualitative approach lie in the more time-consuming analysis necessitated by pulling factual data from long, albeit highly structured, interviews. Gathering unambiguous factual responses about processes and outcomes in each clinic is obviously more difficult with multiple informants and purely verbal data collection.

### **Sample selection**

The process used to identify the clinics and set up the interviews was:

1. Discussion with Advisory Group members and with the team led to the identification of 47 clinics as possible research sites, from an original list of all HFEA-approved clinics in the UK. Desk research into the profiles of these 47 clinics assessed the size of clinic; the range of services offered; the balance of NHS and private patients; the reputation regarding liberal or a more restrictive approach to accepting patients for treatment; and the location of the clinic. This research generated a portfolio of information about the variety of salient features of all possible research sites and enabled the research team, in conjunction with the Advisory Group, to exclude some clinics from this initial round.
2. Following further discussion with the Advisory Group, this group of 47 was reduced to 44 clinics to approach with an 'in principle' request that they consider participating in the study. We over-sampled in anticipation of some clinics being reluctant to commit time to the study. [See Appendix 1 for in-principle letter/email]. Thirty-four in principle requests were sent via email from two members of the Advisory Group: it was thought that this personal contact from a fellow professional would maximise the likelihood of a positive response from busy clinicians. This proved to be a valuable strategy for making first contact. The remaining 10 clinics were contacted directly by the researchers. Of the final 20 clinics recruited to the study, 17 sites agreed to participate as a result of personal contact from an Advisory Group member.
3. Once in-principle agreement to participate was obtained, the research team emailed an invitation letter [Appendix 2] and an Information Sheet [Appendix 3] to the initial contact at each clinic, with a request that they either circulate it to colleagues or provide colleagues' email addresses for the research team to contact them directly. It seems that at a number of clinics, participation in the study was discussed at clinic team meetings and staff volunteered to participate. Further contact between the research team and the clinics was conducted entirely via email, with minimal demands placed on clinic staff time.
4. Before an arrangement could be made to visit an NHS clinic, local R&D approval had to be gained from the relevant Hospital Trust (see below for further discussion of this requirement). Once R&D approval had been provided and a sufficient number of staff had agreed to be interviewed, a convenient time to conduct the interviews was then arranged. Visits were usually conducted on one day, although some London clinics were interviewed over a number of visits. In some cases, individual recruits were unavailable on the day of the visit due to patient commitments, but in others,

additional staff were invited to participate where they had been particularly recommended by participants. Occasionally, after an initial conversation with a potential participant, it became clear that they had little or no involvement in the welfare of the child assessment and so it was agreed that they would not participate in the study. Written consent was taken on the day by the researcher immediately prior to each interview. Only one participant requested that their interview was not recorded, the reason for this refusal is not known. Interviews were conducted at 20 clinics, with a total of 66 interviews with staff.

#### NUMBER AND PROFESSION OF INTERVIEWEES AT EACH SITE

CLINIC	Interviewees	Total
1	Doctor/Person Responsible Embryologist Nurse Counsellor	4
2	Doctor Nurse (Person Responsible was unavailable)	2
3	Doctor/Person Responsible Nurse Counsellor	3
4	Doctor 1 /Person Responsible Doctor 2 Counsellor Embryologist	4
5	Doctor 1/Person Responsible Doctor 2 Embryologist, Nurse	4
6	Doctor/Person Responsible Nurse Embryologist 1 Embryologist 2 Counsellor	5
7	Doctor 1/Person Responsible Doctor 2 Embryologist Counsellor	4
8	Scientific Director/Person Responsible Counsellor Nurse	3
9	Nurse Senior Nurse Embryologist (Person Responsible was unavailable)	3
10	Doctor/Person Responsible Nurse Embryologist Counsellor	4
11	Doctor 1/Person Responsible Doctor 2 Doctor 3 Nurse	4
12	Embryologist/Person Responsible Embryologist Doctor Nurse Counsellor	5
13	Senior Embryologist Nurse (Person Responsible was unavailable)	2
14	Counsellor Scientific Director Nurse (Person Responsible was unavailable)	3
15	Doctor/Person Responsible Nurse Embryologist	3
16	Doctor/Person Responsible Nurse Nurse Manager	3

17	Doctor/Person Responsible Counsellor	2
18	Doctor/Person Responsible Embryologist Nurse Counsellor	4
19	Doctor/Person Responsible Nurse	2
20	Scientific Director/Person Responsible Counsellor	2
<b>TOTAL</b>		<b>66</b>

### BREAKDOWN OF INTERVIEWEES BY PROFESSION

PROFESSIONAL	NUMBER
Doctor	20
Nurse	18
Embryologist	13
Counsellor	12
Scientific Director	3
<b>TOTAL</b>	<b>66</b>
*Of these, Persons Responsible	16

The final sample included clinics in all regions of the United Kingdom, ranging from the smallest to the largest type of centre (determined by number of cycles per year according to HFEA 2009 figures). The categories 'NHS' and 'Private' denotes the status of the clinic as part of the National Health Service or a private business; however, most NHS clinics treat a substantial number of self-funded patients, and some private clinics have contracts to provide NHS-funded treatments. One clinic provided only IUI (intrauterine insemination), not IVF (in vitro fertilisation) or ICSI (intracytoplasmic sperm injection), but it was included in the sample because it had formerly been part of a larger clinic that had provided such treatments, and most of the doctors also worked at another clinic which did provide IVF and ICSI. It was also the only clinic not to provide treatment to single women or same-sex couples.

### NUMBER OF PRIVATE/NHS CLINICS

TYPE OF CLINIC	NUMBER IN SAMPLE
NHS	15
PRIVATE	5

### SIZE OF CLINIC (defined by number of IVF and ICSI cycles in a year)

Number of cycles per year of IVF and ICSI*	Number of clinics
0-500 ICSI and IVF cycles per year	6 (including one clinic that now carries out only IUI treatment)
500-1000 ICSI and IVF cycles per year	8
1000-1999 ICSI and IVF cycles per year	3
2000+ ICSI and IVF cycles per year	3
<b>TOTAL</b>	<b>20</b>
<i>*2009 figures taken from HFEA website</i>	

## LOCATION OF CLINIC

Location	Number
London	5
Other	11
Regional Centre	4
<b>TOTAL</b>	<b>20</b>

## Research instrument design and data collection

Our original intention was for individual respondents to spend 60-90 minutes in a tape-recorded interview at a convenient location, ideally the clinic. A draft interview schedule was discussed at the first Advisory Group meeting, leading to the modification of a small number of questions. In particular, the wording of those questions exploring the number and bases for any refusals to treat was altered after it became clear that we were likely to come across very few examples of straightforward denials of treatment. Discussion with AG members also generated further examples of possible circumstances that might give rise to welfare of the child concerns, thus expanding our list of prompts and probes to be explored. A question was added concerning the administration of the Agreed Fatherhood Conditions, as this had been overlooked in the original draft. After further discussion, a question was also added to find out whether the attitudes of prospective donor-recipient patients towards disclosing their future child's genetic origins could have an impact on the welfare assessment of the patient.

An early idea of using written scenarios or video vignettes as part of the interviews was not pursued as it was felt that there would be too little time available with each interviewee to go beyond the interview schedule. This decision proved to be correct, as at many clinics, not all members of staff were able to give a full hour for the interview. In these cases, key areas of the schedule were prioritised and particular attention was given to questions with greatest relevance to that particular professional. During visits to most research sites, a picture of the welfare assessment process at that clinic was gained from the interview with the person most closely involved in overseeing the assessment of new patients (usually the Person Responsible or the person charged with developing welfare of the child protocols and auditing). Other interviewees were asked questions to confirm this picture, or, where time was very limited, participants were asked primarily for their experiences and views of the welfare of the child assessment process.

Interviews were digitally recorded and transcribed by professional transcribers. During the transcription process and subsequent checking by the research team, scripts were anonymised, with all identifying details removed or obscured. Digital recordings were labelled by site number and interview number to avoid the identification of participants. Any cases of welfare concern discussed in interviews that could potentially identify patients by their unusual character have been altered during writing-up to ensure anonymity.

## Data analysis

The computer-assisted qualitative data analysis software NVivo (version 9) was used to support the analysis of transcribed interview data as this software is well-suited to handling a large volume of qualitative data and allows the categorisation and coding of transcript data. The primary advantage of NVivo is that it allows data to be stored and analysed in a way that allows for consistency and systematic co-working across a team of researchers. The disadvantage is a degree of inflexibility and a lack of suitability for incorporating simple quantitative analysis. In some ways, the software is better considered as a tool for storing and managing data rather than for analysing data such as that produced in our study. Analysis requires a high degree of informed interpretation, which cannot be conducted by software alone.

Data analysis was conducted in two stages. Stage one was an analysis of the factual responses to research question 1 (What are the bases for exclusion from treatment according to each clinic's interpretation of the welfare assessment?) and research question 2 (What is the information-gathering

and decision-making process by which patients are assessed regarding the welfare of the child and accepted for, or excluded from, treatment?). Due to time pressures and for the sake of clarity, it was decided that only the transcripts of two key informants would be selected from each clinic to gather the relevant information about the welfare assessment process. The key informants were selected on a clinic-by-clinic basis, identifying those respondents closest to the welfare of the child (WOC) process and with an overview of its operation at their clinic. This was typically the Person Responsible plus whichever other staff member was most involved in WOC assessment: this could be a nurse, embryologist or counsellor, demonstrating the variation in the way assessment operates at different clinics. The sections of the interview schedule that asked about these areas elicited complex responses varying between precise answers to specific questions and lengthier descriptions of organisational processes. The analysis sought, however, to quantify some responses and categorise others in order to compare interpretations of the guidance framework and its implementation across the sample.

A thorough reading and interpretation of transcripts was required in order to balance descriptions of how the welfare of the child assessment ought to work, according to clinic protocols, with accounts of what might actually happen on an everyday basis. Analysis was not always straightforward because of this. In retrospect, this factual data, suited to quantification, might have been better gathered using a brief questionnaire, administered prior to the qualitative interview; however, this would have taken up additional time. Responses to the factual questions were also often inextricably bound up with elaborations that would feed into the qualitative analysis.

Stage two of the analysis was a thematic reading of the more subtle responses to questions 1 and 2 and the opinions expressed in response to question 3 (What are the views of clinic staff about the changes in the welfare clause and the current regulatory framework?). These responses were inevitably convoluted, complex and sometimes contradictory. Overall coding was constructed around the questions in the interview schedule, but as the analysis progressed, patterns to the responses emerged which allowed a more thematic categorisation of individual responses, individual respondents, professional groups and clinics.

## **Ethics**

We allowed a cautious five months to identify the clinics where fieldwork would take place, given that we knew meeting NHS requirements can be a lengthy process. There were two stages to the approval process. First, national research ethic committee approval was required as the research would involve multiple NHS sites. This approval was granted in May 2011 by the Oxford REC B committee. The committee decided that approval could be granted subject to a small number of minor amendments, primarily to the wording and layout of documents to be used in the recruitment of the sample and the provision of some further documentation concerning university data protection policies. These amendments were made very quickly, making it possible for final approval to be granted within four weeks of resubmission.

The second stage of approval required consent from the R&D office of each NHS research site. It also required completion of the NHS Passport process, to allow the researcher access to NHS premises and staff. These submissions were made as soon as in-principle agreement was gained to participation from each clinic; however, the speed with which these applications were dealt and the degree of communication required between the research team and each R&D office varied enormously. Some R&D offices took a matter of weeks to respond and to issue approval, while others were either unresponsive, requiring up to eight months of chasing, or demanded further steps to be taken, such as the provision of locally-headed documents, the completion of additional paperwork by local clinicians (something we were keen to minimise) and the completion of Good Clinical Practice training. The problem of delay seemed to be exacerbated by understaffing or by an inability of the process to distinguish between clinical trials research and far simpler and less risky qualitative studies with no patient involvement. Our experience of the approvals process has significant implications for the conduct of research, in particular, the allocation of resources to the approval process relative to other stages of the research process, and the impact this has on budgetary issues.

## 5: Study findings

### 5.1 How the welfare of the child assessment is carried out: overview

#### 5.11 Informing patients of welfare of the child requirements

Patients are first informed about the welfare of the child (WOC) assessment via information packs usually provided by clinics in the early stages of contact or downloaded from the clinic's website. Some clinics encourage, and in some cases require, new patients to attend a Patient Information session during which a clinic counsellor or a nurse will speak about the welfare of the child assessment as part of a longer introduction about the treatment to a group of prospective patients. In general, clinics use the HFEA leaflet<sup>16</sup> explaining the welfare of the child assessment or have incorporated the HFEA's wording into their own literature.

Staff often commented that the welfare of the child information leaflet and the patient self-declaration form constitute just one small part of a large amount of literature patients are given to read, and forms they are required to complete, before they can proceed to treatment. This context means that the WOC assessment was not felt to be uppermost in patients' minds as they first attend a clinic. Although almost all the respondents thought that patients did not find the welfare assessment off-putting, most could give one or two examples of patients who raised objections to being screened in such a way:

*I don't really think patients have any serious misgivings about the form. I think they see it as an exercise...some people do turn around and say, 'Why have I got to do this when if people conceive naturally, they don't have to fill out this sort of form?' and I think once we explain that it's because, you know, we are the sort of third party, if you like, and we have to be seen to be being responsible in our quest to help them conceive. I think there's an understanding there but I think a lot of patients do feel, you know, that it's not necessary. They don't understand...they don't feel that we should have to go these sort of lengths to complete all these forms just to help them. (Site 16, Nurse Manager)*

*I think a number of patients certainly feel that it's a bit...maybe an imposition to be asked some of those questions when others who can conceive naturally aren't...asked...those sort of questions. But the majority of them do understand why they're being asked. (Site 2, Nurse)*

This respondent thought that the recent changes in the Code of Practice (outlined, above, in Section 2) had lessened patients' objections to the assessment:

*R: I think there are always going to be some patients who feel like it's an unnecessary intrusion and certainly there was prior to the regulations being adjusted slightly – the law's been adjusted slightly – there was an issue, I think, with a lot of patients feeling like it was overly intrusive. That seems to have gone away now. I don't know why. It's sort of gone off the boil.*

*I: Right. Was this prior to 2005 when it was more of the GP process, or...?*

*R: Yeah. Yeah. I'd say it was prior to the GP process coming to an end, but I'm not aware of any patients recently who've actually raised any concerns. (Site 18, PR)*

#### 5.12 The welfare of the child patient history form

There was a fairly high degree of homogeneity in practice across the clinics, but a few noteworthy exceptions emerged from either interviewees' descriptions of the process, or from analysis of the clinics' welfare of the child protocols. A few clinics had interpreted the HFEA Code of Practice in quite different ways. One clinic, for example, had continued with their assessment process relatively unchanged after 2007: they were still routinely contacting the GPs of all patients to ask for their confirmation that there were no welfare of the child concerns:

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<sup>16</sup> [http://www.hfea.gov.uk/docs/welfare\\_of\\_child\\_leaflet.pdf](http://www.hfea.gov.uk/docs/welfare_of_child_leaflet.pdf)



*In addition the [name of clinic] Unit requires the prospective patient(s) to have the [unit's] welfare of the child pro-forma completed by their General Practitioner. This is so we can ask about potential welfare of the child issues from their General Practitioner's perspective.<sup>17</sup>*

Other clinics also routinely contacted patients' GPs by letter to inform them that the patient was presenting for treatment, but with an additional final paragraph asking the GP to contact the clinic with any welfare of the child concerns they might have about the patient. However, unlike the previous system, the absence of a response from the GP was assumed to mean that there were no welfare of the child concerns, whereas previously, clinics were obliged to chase a response and felt unable to proceed to treatment until it was supplied.

In general, the procedure was use a form as the standard means of making WOC assessments. Nine clinics (almost half of the sample) used the Welfare of the Child Patient History form<sup>18</sup> provided by the HFEA, to be completed by the patient at an early stage of contact. Patients are generally encouraged to complete the form at home with each partner filling out the form independently; however, one clinic preferred patients to complete the full pack of history and consent forms in the waiting room immediately prior to a first appointment to ensure that all forms were completed and none were lost.

The HFEA form asks patients to declare a 'yes' or 'no' answer to seven questions:

1. Do you have any previous convictions relating to harming children?
2. Have any child protection measures been taken regarding your children?
3. Is there any serious violence or discord within your family environment?
4. Do you have any mental or physical conditions?
5. To your knowledge, is your child at increased risk of any transmissible or inherited disorders?
6. Do you have any drug or alcohol problems?
7. Are there any other aspects of your life or medical history which may pose a risk of serious harm to any child you might have or anything which might impair your ability to care for such a child?

The form asks patients to provide details if 'yes' is answered to any question. Each patient (both partners in a couple, and all parties in a surrogacy arrangement) must sign the form and a second section is used by the clinic to detail any further action taken. Most interviewees thought that the form was clear and that patients did not experience any difficulty understanding it. If patients did struggle to understand the form, they were guided by a doctor or nurse at the point when the form was checked during a first or second consultation. We detail this process of risk assessment further below, but for now comment on variations in procedures, and commentaries on rationales for these variations. Ten clinics had created their own version of the HFEA form, most of which used identical or very similar wording, but with some significant questions added, as we now describe. Finally, one clinic had decided not to use a form at all, apparently in reaction to the pre-2007 way of performing the WOC assessment:

*We used to use a very formalised assessment of welfare of the child and we started doing this 10 years ago, maybe, and it involved two questionnaires, one that was given to the patient and one that was given to the GP and they more formally asked specific questions about issues around welfare of the child and we did it for several years and we ultimately dropped...we ultimately stopped doing it. Because it yielded very little real information. It didn't change any decision-making and indeed was seen by the patients very sensitively. Patients felt that they were being judged whether they would be good parents or not and, you know, for somebody conceiving naturally outside on, you know, the local street, nobody gives them a questionnaire to ask about these issues so people were feeling slightly discriminated against. It was...there was quite a lot of bad feeling about it and also there was quite a lot of bad feeling from GPs so we almost felt we were in a...a slight no-win situation in that we were performing an exercise which didn't seem to be that helpful and was upsetting people so we stopped doing that formal assessment.*

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<sup>17</sup> From the clinic's protocol 'Criteria for Access to Sub Fertility Service'

<sup>18</sup> [http://www.hfea.gov.uk/docs/Welfare\\_of\\_the\\_child\\_Aug\\_2010.pdf](http://www.hfea.gov.uk/docs/Welfare_of_the_child_Aug_2010.pdf)

*We've got something now on our general patient questionnaire which instead of being a separate form, now just says, 'Are there any issues of concern around this?' So we have become more...we've become less stringent and less formalised in our assessment. (Site 17, PR)*

#### a. Relationship stability

Four clinics included questions on their welfare of the child form, asking patients how long they had been in their current relationship and whether both people in the couple lived at the same address. If they did not cohabit, they were asked to provide a reason. It was not generally clear from the interviewees' accounts whether this question was asked primarily because of PCT funding requirements, because of a clinic's own protocols, or because of welfare of the child concerns. As we detail further elsewhere, relationship stability was seen by some respondents as a welfare of the child concern, necessitating further investigation by the clinic counsellor, although the HFEA's report *Tomorrow's Children* (HFEA, 2005) concluded that relationship stability, commitment to having children and the age of either parent should not be considered social circumstances 'likely to pose a risk of serious harm'.

Cohabitation was seen to be the simplest way of assessing this stability. It was again often unclear whether the stability of a couple's relationship was really an issue of welfare of the child concern, or whether, in this instance, it was an issue to do with the manageability of the patient-clinic relationship during treatment. For example, 'stability' concerns seemed to be used to describe situations where female patients were presenting with a different partner, or with a partner who was suspected to be a known donor, and in a few cases, with a male partner who did not want a child, and was reluctant to take on fatherhood responsibilities for any child born as a result of treatment using donated sperm. They were also used to describe concerns about couples having significant disagreements or even splitting up during treatment. These were reported to be seen as posing issues for clinic staff in dealing with the couple, and were most often referred to the counsellor. Couples experiencing difficulties were, however, talked about sympathetically, with a strong recognition that infertility and fertility treatment could place considerable strain on relationships:

*I think they would tend to be seen by us just to see what's been going on in a sense, to see, especially if there's been a drinking issue, to see if we can explore why they are drinking. I mean, you know, fertility...for couples who've been trying to conceive, it puts such a strain on the relationship and on the individual, so sometimes you know, people, and I suppose it goes opposite of everything that they should be doing, but you know they tend to feel that they need some help to get through it, so that will just be a counselling issue. (Site 7, Counsellor)*

This counsellor was asked by a clinician to assess the stability of the relationship of a couple presenting for treatment, but found this difficult as cohabitation was not necessarily a good measure of stability.

*But then some...some couples don't live together...And then, OK, yeah, that's... I guess that goes then maybe to the financial officer...And I'm sure if you spoke to our financial officer...she does have to go through this for funding...Now I've had to talk with my colleagues sometimes – my counselling colleagues – and say, 'How do you define a couple?' And, you know, a social worker said to me, she said, 'Well I think it's whether they actually eat at the same table.' And then somebody else said, 'Well it's whether they share a bed,' but they're not...that wouldn't tell you that they're a couple, would it. Somebody said, 'Do they share a TV licence?'...You know, you could have a girlfriend and a boyfriend – and I've had this before – a girlfriend and a boyfriend who've been together quite...long term, don't actually live in the same house. She lives with her parents, he lives with his parents because it's just easier for their benefits and if they...and when I said to them, 'Well surely having a child together, it is better a supportive, stable relationship for you to actually share a place together', and they said, 'Well when I get pregnant then we'll be found a place together', so yes, you could say it's a financial...But is that for us to say that they're not a couple? They've been in a long term relationship but they don't actually live together...I mean some...clinics...some units do say they have to have the same address. (Site 20, Counsellor)*

## b. Existing children

Although past conceptions and births are clearly significant to a medical assessment of currently infertile patients, and this information would be gathered from referrals and during medical history-taking, there is an additional, but slightly confusing significance to the question some clinics asked about existing children from the current or previous relationships. If any of these children did not live with the prospective patient, they were asked to explain why not.

Having existing children living elsewhere could be taken as an indicator of children having been taken into care, or custody not being granted, the first of which might relate to Question 2 of the patient history form, as above (and the second of which was seen as more significant for mothers than for fathers). Again, from the interviewees' narratives, it was not clear whether this question was required for funding purposes or as part of an interpretation of the welfare of the child assessment requirement.

*I: So there's questions that are in here that are not on the HFEA form, 'How long have you been living with your partner?' 'Have you had any children in this or any other relationships?' 'Have you any other children living with you at the moment?' So these are WOC questions, not funding-related questions?*

*R: They are WOC questions because, you know, the recommendation is that we treat people who are in a stable relationship and the ethics committee here said, you know, it considered a stable relationship where two partners [are] living together for at least a year, so that's why we're asking how long they've been together. If they have any children, it's not automatically a WOC, but if they are not living with them then you know it could be highlighting issues, why haven't they got custody of the children? I think here we're aware that there might be a difference between men and women because if a man answers, 'yes I have children but they are living with their mother', we don't assume there is any issue, but if it's a woman who has children under the age of 14 who are not living with her, then we may assume that there may be issues...*

*I: And does the PCT provide funding for people who've got children?*

*R: Not generally...but there are exceptions. (Site 14, Counsellor)*

## c. Criminal convictions

Although the HFEA form restricts its question about convictions to those related to harming children, in their own forms, a number of clinics broadened this question out to ask about convictions for offences related to 'harming others', for 'sexual behaviour or violent offences' or even to 'any criminal offence'. According to staff at clinics where the latter question was used, this sometimes led to patients 'confessing' to speeding fines or other traffic offences, which were dismissed as irrelevant by clinic staff, or to other more serious crimes that might lead a further WOC investigation.

## d. Other additions

One clinic was in the process of updating its welfare of the child protocol and had quite extensively expanded the questions on its welfare of the child form to include a question about average weekly alcohol consumption (including a pictorial guide to alcohol units); a question about past or present use of recreational drugs; and a question asking whether the patient had ever followed a detoxification programme. The patient was also required to provide detailed information about any medication for depression, including the product name and dosage (information which would presumably also be captured in a medical history). According to the lead counsellor, the rationale for these amendments was not to pick up on more patients as potentially problematic, but to allow nurses more effectively to filter out patients who were not of concern. It was felt that too many patients were being referred to the counselling team for further assessment on welfare of the child grounds.

## **5.13 Who assesses the form?**

In general, forms were checked either by a nurse or a doctor at the first consultation. The member of staff would look over the form in the presence of the patient (usually in context of a 'consents

session', where all required HFEA forms are gone through), checking that all questions had been answered and querying with the patient any questions to which a 'yes' had been given, or reconciling WOC form responses with information given in other history-taking. In most clinics, a professional would sign the form to say that it had been checked, even though this is not specified in the Code of Practice and there is no space for a professional signature on the form. Staff tended to think that 'signing off' was something intrinsic to their professional training and to not do so seemed unprofessional.

Should there be any 'yes' answers, the member of staff dealing with the patient would ask the patient's consent to approach others within or outside the clinic for further information. Who subsequently followed this up varied considerably depending on clinic protocol, and on the nature of the concern: at one clinic the PR assessed every form with a 'yes' response; at another, the nurse checking the form would make initial enquiries to the patient's GP if appropriate; elsewhere, the consultant concerned would take things further; one clinic referred all cases of concern to the counsellor; and a few clinics routinely discussed all WOC issues at their team meetings.

#### 5.14 Who assesses risk?

Although the mainstay of the formal WOC assessment process was the use of a form, the culture of most clinics was such that, additionally, all involved in face-to-face contact with patients explained that they felt that they had welfare of the child obligations, whether or not they were responsible for checking the WOC form or taking patient histories. This responsibility was often described as extending to include reception and administrative staff, and laboratory staff who might deal with patients either at the clinic or over the telephone. If patients were upset or angry, or revealed information about their circumstances deemed to have significance, either prior to or during treatment, all staff were encouraged to report this to another member of the team. Multi-disciplinary team meetings (MDTs) were used in a large number of clinics to get a range of opinions involved in an assessment. The rationale for such involvement was partly to get as wide a range of opinions as possible, sometimes including reception and administrative staff and members of the laboratory team as well as doctors and nurses. However, another reason for involving staff was to facilitate the building of consensus.

*I feel confident because it's a group of people and so we try and make a consensus decision but I don't think any person will have hold of the real truth, any person is right, but if we reach a consensus in which we all have a say...it's the best way, isn't it, rather than a unilateral decision where someone would decide based, you know, on their subjective beliefs. (Site 1, Embryologist)*

*I think there have been cases where we've maybe had mixed views within the team. We always used to have a sort of monthly team meeting which involved the whole of the team and I know when I joined because I'd come from a completely different background, I tried to encourage that we discussed patient cases as well as clinical issues at those team meetings because I think it's really important to a) make everybody aware if there are issues that need to be addressed and b) you know, to...get everyone's view on those. It's not just up to one or two or three people...there was one case in the past where we did have quite mixed views as to whether it was acceptable to treat a couple when the male partner had terminal cancer...And I know that the clinician had very strong views. I felt very strongly the other way and to discuss it at a team meeting like that, I think it's really beneficial because it just makes you, you know, look at maybe other aspects that you hadn't considered. (Site 16, Nurse)*

The Person Responsible was ultimately responsible for pushing towards a resolution of WOC issues, but there was substantial variation in which staff were involved in further investigations where WOC concerns arose. In some clinics, the lead clinician might get involved in speaking to patients or contacting other professionals such as medical specialists or psychiatrists, but in others, the counsellor took this role. Counsellors tended not to be involved in MDTs unless they were presenting the findings of an assessment counselling session, this would most often be presented in writing.

The involvement of ethics committees was generally regarded as something to be avoided other than in exceptional cases, as it could delay the process of approval or refusal. The role of the ethics committee was described as offering guidance rather than a judgement, and all clinicians described having the option to act upon or reject ethics committee advice. One clinic had an 'in-house' ethics

committee that discussed cases on a far more regular basis. The committee was constituted of staff representing different professions within the clinic, so in this sense was like the multi-disciplinary team meetings of other clinics; however, it also included local GPs, lawyers, former patients and independent social workers, who were sometimes charged with providing assessments of patients, including performing in home visits. This procedure was exceptional.

### 5.15 Further action

As discussed in more detail below, cases of WOC concern could be followed up in a number of ways. Other specialists involved in the care of the patient would also be approached where concerns were based on a medical or psychiatric condition. Social services, probation officers and, very occasionally, the police, could be approached for further information concerning existing children, criminal convictions and other ongoing criminal issues. A couple of clinics asked patients with a criminal conviction to acquire a CRB check, but in complex cases, usually of violent crime, court records and information from the patient's lawyer might also be sought to confirm the details of the crime and to satisfy the clinic that the patient's behaviour towards their adult victim need not be read as an indication that they posed a risk towards children. This information would tend to be brought back to a team meeting before deciding whether treatment could proceed. Refusing treatment was seen as a very serious decision, to be taken only after substantial investigation and discussion with the patient themselves, amongst the clinic team and with the input of external expertise. The first step was usually to contact the patient's GP, and counsellors were also reported to play an important role. Given this, and the attention drawn to GPs' role and counsellors in previous studies, we provide some commentary of these areas of further action here.

#### General Practitioners

Some General Practitioners were described as providing significant background social information about patients during the referral process, but this was understood to vary depending on the GP and on the patient. However, the patient's GP was always the first port of call for seeking further information should a welfare of the child concern arise. There was a prevalent view that GPs know patients best, although this was qualified by statements that male patients often had little or no contact with their GPs or that some patients, particularly in inner-city areas with more mobile populations, may have shorter-term relationships with their GPs:

*You may find that one partner goes to one GP and the other partner has another GP...he's got children, he may come from another area or from another country and the GP only knows what the man has told him, so if the man – it's usually the man, it's more difficult for a woman to say, the man will say yeah I've got children, but oh no they're not my children, or even a woman will say actually, she's an adopted child – so they do – and I suspect the information is getting out there now, so they fill the forms out more cleverly, I suspect. (Site 1, Doctor)*

#### Counsellors

The degree to which counsellors were involved in the welfare of the child assessment varied considerably from one clinic to another. In one very large clinic, a team of counsellors seemed to be at the centre of the clinic, responsible for drawing up assessment protocol, routinely taking on further investigations, and dealing with informal nurse queries about issues raised in patient consultations. Similarly, at a different clinic, the counsellor's office had a very central location, enabling her to observe patients in the waiting room. Any patients about whom other members of staff had any concerns would be chatted to by the counsellor and possibly encouraged to attend formal counselling sessions. In marked contrast, at other clinics, counsellors were located off-site, either visiting clinics once or twice week to see patients at pre-arranged appointments for implications or therapeutic counselling or located entirely off-site. In one clinic, information about donation was routinely conveyed by nursing staff, and patients were referred to the offsite counsellor only if they requested therapeutic support.

Typically, besides providing 'therapeutic counselling' (described by respondents as voluntary counselling for the purpose of support or for further exploration of issues raised by treatment), counsellors were also asked to conduct 'assessment counselling' with patients about whom further welfare of the child investigations had been triggered. All counsellors described telling patients that

although counselling sessions are generally confidential, if anything of concern arose, they would be obliged to take that information to the doctors, with the patient's consent. For many of the counsellors, this duty to inform on welfare of the child issues existed in tension with the standard counselling practice to maintain client confidentiality:

*I don't feel in a way it is like normal counselling because I think there is tendency for them to be the good patient and give out the right answers sometimes because they are aware that if they say anything that's going to sort of make alarm bells ring that I'm going to be the one that's going to talk about that...so it's a different kind of counselling. It's not really counselling; it is assessment. But sometimes it can cross over within that session when we're going through all the implications, it can cross over into counselling, definitely. (Site 3, Counsellor)*

*I think it puts the counsellor in a very difficult position...she tells us how she does it. She says, you know, 'there are potential issues here and I may have to take this further,' and we rely entirely on that but they are extremely...I mean they're totally different. (Site 4, Doctor)*

*This is a very different role. This is completely away from my counselling side, although you use obviously all your counselling skills to elicit information to see what's going on, to see what's not being said, but the patient considers you to be kind of a judge in a sense and, really, to a certain extent you are, because you then determine whether or not something else comes of this matter. (Site 7, Counsellor)*

A small number of clinics were able to provide more than one counsellor to enable the distinction between 'therapeutic', 'implications' and 'assessment' counselling to be reinforced, but this was unusual. The obligation explicitly to assess patients for welfare of the child issues was seen by some counsellors as being even more in conflict with the principles of non-directive, person-centred counselling, although others felt that this could be negotiated:

*I would be very explicit with the patient what I was doing. I would be very explicit about what my role was and I would also explain to the patient that I am not singlehandedly going to make a decision but it is actually going to be the team who makes the decision, but that the information that I give them will be part of that decision making process and that I do a written report, but my patients always see their written reports before they go to the team so that they are completely open. (Site 10, Counsellor)*

*I had no difficulty between the therapy role. I mean it's got to be... you've got to kind of become skilled and it's a bit...that's not easy but the therapy role with the authority role and I think that is a difficult one but I think it can be done. Honesty's a lot to do with it. (Site 4, Counsellor)*

*Well, in the assessment sessions I am asking direct questions and I'm gathering information and I'm also explaining the reasons that I'm asking these questions; what they are about and I always give them a copy of the protocol as well so that they're very clear that this is what I'm doing, this is what can happen that I'm going to be reporting back: I may be making a report. I want to gather some information so that I can report back to the team...that the Act of Parliament says that we have to act in the best interests of the child and that if it is considered by the team that it would not be in the best interests of this or any other child, that we would refuse treatment and that they have the ability to appeal that decision to the Ethics Committee, and just give that information and I talk this through as well before I start so that they know what this is about. (Site 12, Counsellor)*

Counsellors tended to feel that more patients would benefit from receiving supportive counselling to cope with treatment, but were often uncomfortable about taking on an assessment role. Some counsellors felt that clinicians often had unrealistic expectations of their ability to perform risk assessments but also misunderstood the purpose of counselling.

*I don't think it's right in this setting...you can identify risk but I don't think it's right for the only counsellor in the clinic to be doing risk assessment. (Site 4, Counsellor)*

There were some interesting parallels drawn between risk assessment in a social work context and the risk assessment of the welfare of the child assessment. In common with some of the other

counsellors, this counsellor had a social work background and it was this training that made her feel more confident of performing welfare of the child assessments:

*I think probably through my other post I do more risk assessment than I do here in terms of training; so I feel more equipped to do it. If I just worked in this field I don't think you necessarily get the training for risk assessment to do this job. (Site 7, Counsellor)*

Counselling training was not understood by counsellors as providing the necessary tools for conducting risk assessments:

*R: If it's the clinician that's asking then usually it's about a relationship issue.... Well no, that's not true; I suppose they have asked me for things like how a patient could cope if they had a disability. Sometimes I don't think always they're appropriate and I've had requests to do an assessment on somebody who's schizophrenic or has bipolar. I mean, and I don't at all see those as appropriate, although I can understand perhaps they're looking for a social assessment of how they would cope potentially with a child.*

*I: So you don't think it's appropriate that you're called upon to do that assessment, or you don't think the patient should be assessed?*

*R: I'm saying that I don't think I'm always the appropriate person to be called on. I mean I can do a social assessment but... I can only do it within the limitations of my experience. I mean I'm not a medical person. I'm not a psychiatrist and I'm not a social worker. I think of lot of counsellors are social workers and I think they maybe have some more experience. (Site 20, Counsellor)*

Both of these PRs thought that the US model of using psychological evaluations of all patients should be considered in the UK as an alternative to the welfare of the child assessment.

*R: Every single patient has to do a standardised psychological evaluation, which is somewhat different from counsellors as you probably know. So you're basically doing something that's been pretty well validated and it looks at anxiety and anger and all these sort of things and people who score, you know, the wrong side of the line, you know, have more investigation and they're refused treatment.. I think that would be a deterrent...and particularly since you can go somewhere else very easily. I don't know; I think it's not a bad idea and I think that would [be] a standardised way to pick up a lot of these welfare of the child issues which are being picked up anyway.*

*I: What's the rationale in the States? Is it 'Are we going to be able to treat you as a reasonable person?', or is it, 'Are you going to be an OK parent?'*

*R: I think it's a mixture of, you know, are you going to be a compliant patient who's going to get the best result by working with our team?...and there might be an element of judgement in it because it was a mid-Western State, might have been a little bit judgemental. Welfare of the child but not by that name. Welfare of the patient but not by that name. And a little bit of covering for the doctor...But I think it was a mixture of these things. It's not driven by one thing. (Site 8, PR)*

*R: I think we use counselling sometimes inappropriately as a profession in that we use it as an assessment exercise, so I'll say to [Counsellor's name], 'I'm really worried about this couple. Can you see them?' and actually that's not what counselling's all about. Counselling's there for the benefit of the couple whereas I'm using it...to make a psychological evaluation of whether I think this couple are bonkers or not and so, you know, I'd be much more comfortable using the American system. So in the American system, they go for a psychological evaluation and that's what it's called and that's what it is and everybody is very upfront about it, whereas here it's called counselling and...so I actually think there is a place here for a psychological evaluation but we just tend to call it counselling. The difficulty with counselling is it's genuinely usually only successful if it's directed by the couple and they want it.*

*I: But that psychological assessment, though, what is it evaluating? Their ability to cope with treatment or them as future parents?*

*R: I think it's... I think on the whole, it's evaluating them as future parents. I think evaluating somebody for their ability to cope with treatment.. although treatment is very stressful and is very hormonally manipulative, I'm not sure if I've.. we've ever had many people where we've*

*been worried psychologically could they deal with treatment. We see a lot of very fragile couples after unsuccessful treatment who have lots of difficulty handling failure of treatment and we've had suicidal people and all sorts of difficult situations where the counselling then does become helpful. I don't know. We used to have four counsellors here. Now we have one part-time.*

*I: Right. OK. And this is not through choice, or is this...?*

*R: Cost...Purely through cost. (Site 17, PR)*

Overall, as the above summary of WOC assessments makes clear, consideration of the welfare of the child potentially born as the result of licensed fertility treatment was considered important and taken seriously across the sample. Earlier in our report, we used the term 'liberalising' to describe one possible intention of the reforms to the COP emerging from *Tomorrow's Children*, yet the obvious continuing sense that assessment of the welfare of the child who may be born from treatment is an important and significant task for clinics arguably calls this description into question, of how things work in practice. We consider this issue further later, below, through discussion of what respondents had to say about the idea that there should be a presumption that all patients should be treated, unless reasons not to treat are clearly identified via the risk assessment process.

One aspect of 'liberalisation' especially central to both legal and policy reforms was the stated intention to address concerns about discrimination against groups of prospective patients, in particular single women and lesbian couples. The balance of the case made from previous research has been that clinics had already become increasingly unlikely through the 1990s simply not to treat these patient groups; that is changes in practice *prefigured* the deletion of the phrase 'the need for a father' from the law, and the directive from the HFEA that discrimination is not acceptable. In this light, we now detail what we identified regarding the approach to these groups of patients, and also discuss what emerged regarding other identifiable patient groups.



## 5.2 Making welfare assessments and ‘problem groups’ of patients

Same-sex female couples and single women were treated by all but one of the clinics, and this clinic did not provide IVF or ICSI to any patients. Clinic staff indicated they were explicitly aware that discrimination on the grounds of sexuality or marital status is no longer considered acceptable in law, or in the way treatment was provided. Even where staff had personal views that were out of step with equality requirements, they made a strong distinction between their personal views and their professional obligations. The Person Responsible (PR) quoted below, who classified himself as having more conservative views, thought that there had been wider shifts in attitudes and in legislation that made refusals to treat more difficult but also unnecessary, as staff who objected to treating particular patients were nowadays in a minority and could make an individual decision to opt-out of being involved in treatment:

*Over the years when I was working much more in the IVF unit, you know, we could see that the positions that we were holding and we held for a very long time, the view that we wouldn't treat same-sex couples and we wouldn't treat single women, and that then came to be challenged by, you know, human rights sort of arguments and things like that and we then had to agree that there were some people who had worked in the clinic...I worked in a clinic for over 20 years and when I came there first of all, I was not in the minority. And most people will have had quite conservative views about who we should and shouldn't treat and then as time goes on, your people, younger people come in with different views and we began to be aware that the shift.. there was a shift in mentality of people and really we would discuss this every three or four years as a group and it became very clear over time that there was a shifting demographic nature of the people that we were looking at, so many more people would be quite happy to treat same-sex couples and once you go beyond 50 per cent then it becomes quite difficult to say, 'No. We won't do it', particularly if you can effectively offer treatment to people and still be able to account for people having conscientious objections. (Site 11, PR)*

Although some clinics allowed staff to ‘opt out’ of treating certain patients on grounds of conscience, there were no recent examples of staff taking up such an option. However, there were still individual circumstances that provoked concern at some clinics more than others; for example, single women were considered completely unproblematic at some clinics but in others, they were still considered to require particular assessment to determine their suitability as future parents. Despite some ambivalence about treating single women, the fact that single women can no longer be discriminated against was cited as the logical basis for other patients going forward for treatment should they request it in the future: for example gay men, single men, transgender people, and was used as a rationale for providing treatment to couples where the father had a limited life expectancy.

### 5.21 Single women

Although single women were treated at all but one clinic, there were varying opinions about this and their treatment seemed to be more contentious than other groups of patients. Some staff felt that single women should be treated like any other patient:

*I: And do single women trigger any different assessment process?*

*R: No, not really. Not really. Not unless they're... you know, not unless they're a single woman with an issue, if that makes sense? (Site 6, Embryologist)*

A number of interviewees were relieved that the old requirement to consider the ‘child’s need for a father’ had gone:

*R: ...the single female thing we've never really had a serious issue. So unless there was other stuff going on. So just the fact that you were a single woman, no. We never had that. Where we had it a little bit was around the law, so you'll remember when the law changed around that where it said...part of the welfare of the child assessment was to take account of the need of that child for a father, which was very contentious and we kind of got around that because we thought it was a load of unnecessary stuff, by saying was there a male role model that*

*could be used? I can remember having these conversations and some of them used to look at me as if I was crazy and then trot something out that they felt we wanted to hear about having a brother who was going to take them to the football and that sort of stuff...And I remember thinking this an inappropriate conversation. (Site 17, PR)*

However, some clinics were still thinking in terms of the pre-2008 framework, despite the change in the law:

*R: And single women, we've always treated single women as well. Not as many, but we have treated some...and obviously it's something that's talked about with them about whatever male figure there may be that again, a child can relate to.*

*I: ...do you find that the new wording which uses the term 'supportive parenting', is that something that is meaningful? Is that what you talk about here?*

*R: I'm not sure what is 'supportive parenting'.*

*I: What would you tend to use?*

*R: I think a male figure...that a child might relate to because I think...well children definitely relate differently to males and females and I think it is important that they are aware of the...the differences...and the different relationships that might develop and the communication, I think, is often different with men and women for a child.*

*I: ...so do you think that the consideration of that could come in within supportive parenting?*

*R: Yeah. Yeah. I'm sure it could, but maybe supportive parenting is not the right words.*

*Maybe it is the right word because I don't know what other term there would be but it's upbringing of the child, isn't it, and recognising that if...it's a single woman or a same-sex couple...that to give a child an all-round life experience and whatever else that they need to be aware of the role of men in society and relationships, I guess. (Site 12, PR)*

Beyond residual concerns about the need for fathers and male role models, issues regarding the treating of single female patients tended to be inconsistent: ranging from worries that some single women tend to not think through the serious implications of having a child – for example the costs of childcare, the level of support needed from family or friends, or the demands a child might place on the mother – to more vague worries that a particular single woman was rather odd and her personal circumstances were not conducive to raising a child. Some felt uncomfortable with what they saw as a sense of entitlement amongst some single women:

*I: And so single women, they are still routinely brought forward for discussion from a welfare of the child point of view?*

*R: Yes.*

*I: And what's the thinking there, do you think?*

*R: It is normally whether they...well, they have to see the counsellor...Because she has to sort of look at whether they've got their coping mechanisms and things. I don't think they any more say that they have to have a male role model. But I mean you might need to talk to the counsellor about that because she's the one that talks to them about that.*

*I: But as far as you're aware they see the counsellor not just because of implications counselling but because of their singleness?*

*R: Yeah, to make sure they've got support mechanisms and things like that, really. (Site 18, Nurse)*

*R: In this team we have one senior consultant who has a very, very open attitude to these things for various reasons and he argues that we should just be treating anybody. And we have others in the team who would argue that actually a single woman, you would need to assess welfare of the child much more carefully so we're constantly trying to balance the opposing views of the different team members.*

*I: And what is the concern with single women?*

*R: Well you have to look at motivation for having children. We have had cases where a single woman has been motivated to come to us to have a child because, not for the sake of having a child, but really it's transpired that they would move into better social housing if they had a child and things like that, you know, so it's looking at the motivation and also some members of the team feel that parents – plural – is better than parent. I don't know. I'm a lay person with regard to that kind of thing. I'm aware of some papers that have suggested that single*

parents, children of single parents don't do quite as well and I'm aware of those that suggest it doesn't make that much difference. (Site 18, PR)

*R: You know, if they haven't had a serious relationship for a number of years, I will sort of, you know, wonder why. You know, is there a commitment issue? You know, a baby is for life, you know, like the dog is for life, not just for Christmas...and what does a child mean for them? Why do they want a child?*

*I: And have you generally found in people's responses a reassuring reason?*

*R: Yeah, usually. It's about the fact that they always wanted to have children and they just assumed it would happen and the relationship just didn't work out the way they wanted and they feel they want to do it before they miss the boat. They're usually in their late 30s. Yeah. I'm trying to think, you know, have I seen anyone that really I felt shouldn't have had a child? Not necessarily, no...I think the ones who genuinely really want to have a child are the ones that come here. It's...because it would be easy for a woman to just go out and have sex with someone they meet to get pregnant – well, maybe not easy for every girl, but you need to meet someone first, but all I'm saying is they're doing it in a responsible way by coming here, so I think, you know, when they start putting that amount of thought and work into it then they are very genuine and committed to that. (Site 3, Counsellor)*

Single women's material resources were alluded to as a factor in their consideration for treatment.

*R: We have certainly refused to treat some single women, although the vast majority of the recommendations of the ethics committee have been to treat but there...there must have been one or two over the years that we've said, 'No, we don't feel that you are in a situation where you could take on pregnancy and a child.' (Site 5, Doctor 2)*

*R: We're looking at why? Why do it on your own. If you look at Susan Golombok's work, the stuff that comes out is heterosexual...well no um...lesbian women couples do the best parenting. Heterosexual couples do the next best but single women struggle. However, that's looking at people being treated with assisted reproduction and that's still probably better because this is a wanted, desired, planned child. That's still probably better than most but I don't think you can tell somebody who wants a baby what actual parenting is like and that's what I try and do: get them to go out and find that information about single parenting. There's one girl that I...it's not that I knocked them back but I really want them to find out the actual practical realities of childcare costs and after two sessions with me this girl who was adamant she had to be treated next month, sort of dropped out because she said she just can't afford to do it, she hadn't thought about this, that, the other. It's practical realities of parenting, yeah, we'll make them go out and look for...if this is implications counselling that's so totally different to pure counselling, so you can actually do all this in the welfare of the child and implications stuff. (Site 12, Counsellor)*

One clinic was, however, still routinely referring single females to the ethics committee:

*So from a personal point of view, I don't think, unless there's anything particularly striking, that they need to come through for ethics committee approval. We did have a debate about lesbian women as to whether or not they need to be there because at one point they were all coming through for the ethics committee as well and we had quite a lot of debate about that and it was...yes, these don't need to come through to us at all and I personally feel that we should be looking around the same thing at single ladies because the clinician can make a judgement as to whether or not he feels that there's adequate support there. I don't think we need to...unless there's something striking, I don't think we need to...there's no risk of...and the Act's there to make sure that there isn't harm – serious harm – and I...my personal opinion is that...that doesn't fall within that remit and so I think taking them to ethics could be described as victimisation but...you've got a range of ages and opinions and people are on the committee, so... (Site 5, Embryologist)*

This clinic's welfare of the child protocol considered the treatment of single women and of patients in lesbian and gay relationships to 'merit careful consideration'.

The use of the new terminology of 'supportive parenting' seemed to be being interpreted by some interviewees as a need for 'supported parenting'. Women seeking treatment on their own were therefore seen as requiring additional assessment to establish that they had in place 'networks of support':

*I: So do you treat very many single women?*

*R: ... not very many but we won't refuse them.*

*I: If they didn't need implications counselling, would you feel that you needed to do some kind of assessment?*

*R: Yes. Yes. Yes. Yes. Yes. Because also about, you know, the.. how supportive the parenting and the structure and the support that they have and all of that. (Site 7, Doctor 1)*

*I: And is there another dimension to the implications counselling because they are on their own?*

*R: I think the dimension there is support more than anything else. I don't think it's anything more ensuing than that. I mean, you know, we've all become a lot more accepting of these things. Support for the woman and the child, should she be.. You know, I mean in any family situation as you take resource out, life can become more difficult. Obviously conflicts are there when people are there but...so I think the studies so far say single people are fine if they have a support network and the children are fine, but not if they're under pressure. (Site 8, PR)*

This seemed to blur the distinction between the wellbeing of the patient and their ability to cope with treatment, pregnancy, and child-rearing, and concern for the welfare of the child. The single woman may not be stigmatised for being unmarried or without a partner, but she did seem to have a tendency to be viewed as particularly problematic, even if not in the posing of any risk of serious harm to her child. There seems to be a residual paternalism in the construction of single women seeking treatment as particularly vulnerable and in need of support. However, this could be seen as legitimate concern by professionals for the wellbeing of their patients.

## **5.22 Female same-sex couples**

All of the clinics in the sample had experience of treating same-sex female couples and the majority of staff were keen to stress that lesbians were treated in the same way as heterosexual patients:

*Two lesbians, single women, no I think we've moved away from that being a welfare of the child issue. (Site 1, Counsellor)*

*We would just treat them the same we would treat any couple. (Site 9, Nurse)*

*We've become much more comfortable treating both lesbian couples and single women and not putting them through any special hoops to jump through to find out whether we thought they'd be good parents or not. (Site 17, PR)*

*Same-sex couples are very much just the norm nowadays. We also changed the paperwork so most of it says patient and partner or female and partner rather than saying female and male because it's quite embarrassing when you're trying to do the paperwork when you've got two ladies and, you know, you're sort of saying, 'Could you...could you sign for the male?' No! (Site 18, Nurse)*

In general, treating lesbians was seen as straightforward, with some respondents keen to point out how 'good' lesbian patients could be as parents because they were seen as well-prepared for parenthood: fully aware of the facts and consequences, equipped with strong support networks, and open and honest in discussions with clinic staff:

*In reality, actually lesbian couples are very well thought out often before they come. There still is an awful lot they have to think about, but...they're often a joy to work with because they really do think about the child and managing difference because they're already managing difference in the fact that their sexuality is different so they're often very, very well thought out but there's still a lot of stuff we need to discuss. (Site 4, Counsellor)*

*...by the time [counsellor] gets to see them for the implications counselling, she's always very impressed with how they've thought that through and, you know, her reports say, you know, Miss X and Miss Y have got a brother here, or...you know, a neighbour or whatever and they've...they've thought about it. (Site 10, Embryologist)*

At all clinics with 'compulsory' implications counselling, lesbian couples were required to go for at least one session, due to their need for donated gametes. Most respondents stated that the need for counselling was derived **solely from the use of donated gametes**, not to deal with any perceived issues specific to lesbian parents.

*I: So they'll be using donated gametes, do they have to go to counselling?*

*R: In exactly the same way as a heterosexual couple. There's no discrimination at all. We've never discriminated against same-sex and you mustn't. It implies that relationships are less valid. (Site 16, Doctor)*

Complications associated with lesbian couples tended to be seen as relating to the donation of gametes rather than the sexuality of parents:

*They get implications counselling, not because they're same-sex but because they're using donor sperm. (Site 7, PR)*

Although sometimes these donation issues were seen as specific to same-sex couples:

*I: And do you think there's an aspect of the counselling that is beyond the donation issue?*

*R: Yes. Yes. I think there is, yeah, because obviously there's.. there's issues about bringing up a child in a same-sex relationship as well, telling the child about that, because we do sometimes have same-sex couples who one will provide the eggs and then the other one will actually carry the child so... so there's all sorts of issues related with that. (Site 12, PR)*

However, despite a general commitment to equality, there was some variation in the way same-sex couples were talked about. A few interviewees spoke about the need for patients and the counsellor to think about 'role models' or 'male role models', reflecting some continuity with previous legislative concerns about the child's 'need for a father':

*I think they go into how people feel about the genetics of it, that it's not genetically your child, and we do quite a few same sex couples so the need of a father figure is gone into, so it is still all discussed really. I think we ask people to think around all these subjects. (Site 13, Nurse)*

Although this clinic no longer saw same-sex couples as necessitating a clinic discussion, nurses who talked patients through the implications of donation also talked of 'male role models'.

*R: We used to discuss all same-sex... it was all same-sex couples and all single women...just a brief discussion saying these are coming forward, has anyone got any objections, when I first started working here – we don't do that any more.*

*I: So that was 10 years ago?*

*R: Yes. We don't do that anymore...Single women, perhaps. I'd have to check...whether we discuss single women...I think it's become more acceptable as we've got more used to it.*

*I: And at the implications session, are you doing...is there much specific to the fact that they're same-sex?*

*R: There's discussion about male role models and stuff like that.*

*I: There is?*

*R: Yes. (Site 15, Nurse)*

In some cases, it seemed that patients either shared concerns about the child's need for a father figure or were aware that demonstrating to clinic staff that they had considered the issue of a 'male role model' might be wise.

*R: ...and also some couples will come forward and they would say, 'We have considered a father figure for the unborn child,' and all of that...*

*I: And people use that kind of language, do they?*

*R: Yeah. Yeah. (Site 7, Doctor)*

*R: I think for me personally it's made a big difference because I am quite cautious how I talk about that now. I think that I used to have the kind of law on my side that I could say well, you know, what are your feelings about the role of men in your life, and where, what do you think of male role models, and kind of get them to talk about how they see it and hopefully elicit from them that they, you know, think it's important. But I suppose I personally feel I have to be much more cautious about that because I don't want to be seen as, you know, I have some agenda, some judgement, some personal feelings about that, so I have changed the way I work with them.*

*I: Do you find that patients sometimes talk spontaneously in the language though of role models?*

*R: Yes, absolutely.*

*I: Do they think that's still what you're trying to get at?*

*R: Some do without even, we haven't, you know, we haven't talked about that at all and some do. But many don't as well. (Site 1, Counsellor)*

The changed legal framework meant that some staff felt that the way they had to act as a professional might be in tension with their personal beliefs:

*I: And do you feel inhibited from doing what you would like to do by that, do you think it is important that there are male figures present etc, are you concerned that sometimes there aren't male figures present or generally are there?*

*R: I think it would be nice for a child to have both sexes in their lives when they're growing up in various forms. I don't have any specific role that they have to play, I don't have any strong feelings about that. I think that probably for the child's sake, if the child's brought up purely in a female environment with only female friends and only – but I think that's rare, I think that's rare, and I haven't really got any evidence because I don't think we really have very much long term evidence of you know, of the effect on children of being brought up in a same-sex relationship, so I don't feel it's for me to judge. (Site 1, Counsellor)*

Only one clinician raised more profound reservations about treating same-sex couples and single women.

*R: I think it's sad because I guess as a father and as somebody who looks at a range of family situations that I know and see functioning, it does seem to me that no matter actually...I mean having only one parent is probably not a healthy thing for a child so having only a man or a woman as being the parent is probably not healthy. And having, you know, deliberately allowing it to be so that women can have children without there even to be a man within that relationship to act as the male figure, I just feel is an unhelpful, unhealthy way to behave and it does reflect the society that we live in, the...sort of the more liberalism that this country exists within. It wouldn't be my morals. But, you know, we...we do recognise and would not withhold treatment from same-sex couples but at the moment we don't treat single women...I will still have some anxieties about the lack of a male in that sort of child's life...*

*I: Do you think it's now difficult to hold your views in the sector?*

*R: So you can have a view on something but it doesn't...that view doesn't stop you from treating people fairly and if those people are entitled to treatment, you treat them. You may sit at the review thinking I don't like this but, you know, that doesn't stop you from treating them or being unfair. And then they wouldn't know that I didn't approve of it and so for a same-sex couple, we would, you know, if you know, I know that we have operated and done, you know, surgical procedures on women in same-sex couples because I'm aware of that – I think that's fine – you know, we're doing this for a reason and they're going to go off and have donor insemination or whatever elsewhere but they need something done first of all. So my view is an internal thing and my expression of what they need to have done is to get it done. (Site 11, Doctor 3)*

Some professionals had more vague ideas about potential issues with same-sex parents that were seen as necessitating further discussion, usually during implications counselling:

*R: The ideas about whether or not they're isolated in their relationship or whether they've got supportive friends, whether they've got family round about, and those kind of things, so that they're supported enough. I think that's the crux of that discussion really, probably.*

*I: And is there still a kind of gender dimension to that? Do people still talk about male role models?*

*R: Yeah sort of. It's not so much role models as having people round about, I think. One of the risks is that they...that they can become isolated in their relationship because they're a lesbian couple and they've quite for themselves and actually don't...don't get out and about and meet people or have no people or have friends or share experience with people so it's as much checking that they've got people around them, I think, and that they're not...they're not stuck... Actually, I think the couples that we've seen have been very straightforward from the point of view of treating them and much less difficult to deal with from that point of view and that discussion point of view than single women, for instance, because they know where they're going, they know what they need, they know where to go to. (Site 15, Doctor)*

However, a couple of respondents shared ideas about the need to assess whether lesbians were 'anti-men':

*R: ...where the child would have no legal father you are expected to have...you need to check out somebody's attitude to men. Is there going to be a balanced attitude to men? That's the only thing I'll check out with a lesbian but if you've got a rip-roaring lesbian couple who are so anti men.*

*I: Has it ever happened? I mean have you ever come across a couple like that?*

*R: I came across one a couple of years ago yeah...she was....one of them was very, very anti men. It was bloody ridiculous and of course it came out that she'd been abused... (Site 12, Counsellor)*

### 5.23 Recipients of donor gametes

Donation of any kind, however, was regarded as raising a particularly complex set of issues, through which patients required guidance. At one clinic, a staff member explained, as part of his account of welfare assessments and whether people are refused treatment:

*Often we postpone treatment. We tell them, you know, wait six months, or we'll reassess in a year. For example, people who need to have sperm donation, we force them to delay for a few months so that we make sure that they've had to time to think through that person rather than jumping into it because it has huge implications, doesn't it. (Site 1, Embryologist)*

Patients requiring donated gametes were, in all but one clinic, talked of as needing to undergo at least one session of what was generally termed 'implications counselling'. The purpose of such counselling was described as providing an opportunity for patients to consider a number of issues that could potentially arise from the use of donated gametes. This tended to be framed as being 'mandatory' or 'compulsory', although the law and Code of Practice determine that while the provision of counselling is mandatory, the take-up of counselling by patients is not:

*So some of them have to go for compulsory counselling, so say if they're having donor gametes or HIV or they've got medical problems we insist they go for counselling. (Site 1, Doctor/PR)*

*Well the counsellor will do some implications counselling and obviously all our patients needing donor gametes will see the counsellor and people who want to be donors will also see the counsellor... (Site 12, PR)*

*It's only donor gametes that require...would require...under the HFEA guidance that would require counselling. (Site 2, Doctor)*

*If any couple are receiving or donating any gametes then we make it a condition of their treatment that they should receive counselling... (Site 5 Doctor)*

*There could be because if the couple, for instance, considering donor gametes, they will see the counsellor as mandatory requirement. (Site 7, Doctor)*

*I know that some of the clinics, and I've been zealous about it here, but [Doctor's name] in particular is very clear that he doesn't want to make it a kind of internal mandatory thing, so they are invited...I think pretty strongly invited to have counselling – implications counselling – but if they say they do not want it, they tick that they've been invited to do it. But they don't have to and that's a great concern for me because the folk who are probably are most resistant to the clinic implications are the ones who probably will say, 'we don't want to' and their fear level will be high for some reason, you know, and that could probably be well supported or helped in a counselling session. But they're the ones that are likely not to come. ...Certainly donation and more especially, surrogacy. And I think particularly if it's a donor surrogate, you know, like a sister or...or a relative – which can work wonderfully well – I think they are naturally naive about the possibilities that can arise and the unexpected feelings that can arise because they know each other terribly well and when a difficulty arises they are very shocked but...but they may not take the opportunity to have counselling because why do they need to? Because, you know, grew up together, we're sisters. The other ones that worry me are the ones who go through COTS which is the surrogacy organisation...our professional body – we pushed for them to make it that all gamete donation were, you know, surrogacy should come through counselling but they backed off and made it that they should be offered counselling so they...they missed an opportunity there. Kind of disappointed on that. (Site 4, Counsellor)*

Although most respondents seemed to be clear that the purpose of implications counselling was to guide patients through both the treatment process and the possible complications of deciding whether, when and how to tell a child they were the product of donor conception, some seemed to confuse this role with a therapeutic or supportive role:

*Well all patients are advised to see the counsellor for support while they're going through treatment but patients using donor gametes, whether it's eggs or sperm, automatically see the counsellor. We try to make it almost a routine thing as part of their routine care to see the counsellor. For those going through...couples or single people going through it's part of the support process from the time that they are inseminated or have embryo transfer through to pregnancy test, we try to get them to see the counsellor at least once, just for some support coping with those days when there's nothing going on and they're just waiting. So we try to get the counsellor involved, you know, right from the very beginning. (Site 16, Nurse Manager)*

Most respondents thought that parents should disclose to donor offspring the nature of their conception, but there was variation in how important this was felt to be and in how far the clinic ought to go in encouraging parents to disclose. All interviewees were asked whether patient attitudes towards disclosing to their child the nature of their conception could ever become a welfare of the child concern, and whether the contents of implications counselling session could become shared as welfare issues:

*I mean I haven't sat in with the counsellor but my understanding is that she says, 'you really need to tell your children otherwise you're carrying a lie the rest of your life if you want to do that'. (Site 3, Doctor)*

*No, it's not a welfare of the child concern as far as I am concerned. (Site 12, Counsellor)*

*It's explored but if they want to exercise their right not to tell the child, we have no issue with that. (Site 18, PR)*

*I don't think that should become an issue because that is...they can't force someone to do that even after their counselling session. (Site 6, Doctor)*



*...it is a bit of a welfare of the child issue but it's not a safety kind of sending parent to jail kind of issue at all, so the discussion...they will have that discussion about telling. We've no control over that ultimately, so it's not a bar to treatment at all. (Site 15, Doctor)*

Some respondents highlighted that for patients of particular cultural backgrounds where donation was stigmatised, disclosing would cause huge problems within the family and broader community:

*You have to respect it. You have to talk about disadvantages but equally with the Asian couples um...the disadvantages for them are huge. (Site 12, Counsellor)*

*I don't think one can see it in black and white because we get people from different cultures here and in certain cultures – I'm thinking of certain parts of Africa – you know, it's a huge shame not to have a child and if no-one else knows then there's no chance of the child finding out. (Site 3, Counsellor)*

One interesting response suggested that a discussion about disclosure was a 'doorway' into a further exploration of the couple's suitability for treatment:

*I: ...is there any way in which the couple's attitude towards disclosing to the child, so in an egg-donation scenario, that a couple's attitude towards disclosing the child's conception would actually become a welfare of the child concern? If say in implications counselling, one of the couple, or both partners were absolutely resolutely against...*

*R: ...actually, yes, I think it would. And that was what I meant about the doorway in. So the doorway in is before we start just going, 'Mmmm, I wonder if they're quite normal,' and, you know, and all that sort of stuff, just by having the conversation of, 'So are you going to tell them?' Now I think different counsellors have different levels of direction on that. I know they're not supposed to be directed but I know for a fact that some counsellors are quite liberal about this and some of them are, you know, they've totally bought into the idea that you must tell the child immediately...I think I've heard our counsellors say in the past, 'There was a little bit of reticence about telling them.' Now obviously we can't force them. There's no law and all that sort of stuff but certainly a flag's going up if someone's saying no, or there is a difference in the couple so that says something else, doesn't it? That's like the parenting styles are very different and that could become conflict...So yeah, automatically that's welfare of the child concerns.. I wouldn't say in itself the fact that the child isn't going to be told, although I think one could make an argument to say that is...do you know, that is...the welfare of the child is not being considered appropriately. (Site 8, PR)*

## **5.24 Surrogacy**

Very few clinics seemed to be dealing with many surrogacy cases. This was attributed to the complications of arranging and sustaining surrogacy arrangements. Where surrogacy occurred, all those involved, including the surrogate's partner if she had one, would have to be assessed by welfare of the child criteria. This was explained as necessary in case the surrogacy relationship broke down and the surrogate and her partner ended up keeping the baby. Intra-familial surrogacy and donation were both generally described as being more straightforward than extra-familial arrangements.

## **5.25 Gay men, single men**

Only a very small number of staff (at three clinics) had experience of treating gay men and none had experience of treating a single man. The low incidence was partly explained by the difficulty of making and sustaining surrogacy arrangements, but also the fact that gay or single men would not yet expect clinics to provide treatment. Interviewees generally thought that treatment of such patients would be possible, albeit following majority agreement being reached in discussions amongst staff within the clinic and possibly following referral to an ethics committee.

## **5.26 Transgender patients**

Only three clinics had provided licensed treatment to transgender patients, but a larger number had provided or discussed the provision of sperm storage to pre-operative transgender men.

*R: We actually have a couple who had embryo transfer recently where they were both female. One of them became a man. They're now married, or in civil partnership and we've treated them as a heterosexual couple, using donor sperm.*

*I: And are there any other additional welfare of the child concerns there?*

*R: For us, not really. No. I mean they've had so much counselling about her becoming a man and, you know, those issues were addressed at consultation and they were so strong and so together and they've gone through the whole...you know, taken years to get to the point where he had a sex change and was now most definitely a man that we didn't really feel that that was an issue that we needed to address, apart from being aware of it and, you know, the making sure that they had had the appropriate counselling and now that they were looking at having a child and that this may be something that they may or may not want to tell the child at some stage, as well as the fact that they used donor sperm and maybe, you know, give the reasons why. So those were all discussed at the counselling appointment. (Site 16, Nurse)*

*Many years ago we had a gentleman...it might even be 18 years ago – a long, long time, and it's probably not relevant for you, but one couple in whom the male partner was transgender but we did not know at that time. We treated them successfully and they had a child but they only came to light because of a newspaper article some 18 years later. (Site 5, Doctor 2)*

*R: ...and we've treated couples where we've had...where they're effectively a woman with a transgender male...*

*I: Female to male?*

*R: Female to male...we treat them as our same-sex couples in that the...So two women together only one of them's a man and we have two...a man and a woman together, only they're both women...Pretty straightforward, really!*

*I: So that gets discussed at the MDM [multi-disciplinary meeting]?*

*R: Yes. If there's any particular issues that comes from that and I think the people that we've dealt with, I think, in that setting is that straightforward...we don't take all the lesbian couples now to the MDM for instance. There was a while when we did, but they're so straightforward, I mean nobody's objecting.*

*I: When did that stop?*

*R: Oh several years ago now. (Site 15, Doctor)*

While sperm storage was not thought to be problematic and patients looking to preserve their fertility in such a way would not need to go through a welfare of the child assessment, most clinics expressed the view that should the use of that sperm be required in the future, there might need to be clinical discussion and perhaps referral to an ethics committee, generally to allow for staff to express reservations and for the novelty of the treatment scenario to be recognised.

## 5.3 Assessing risk of serious harm

The welfare of the child assessment now centres upon the requirement to work to identify patients judged to pose a **serious risk of harm** to a future child based on their past or present behaviour or circumstances, and those who are **not able to provide a stable and supportive environment** for a child. We now explore what this study detected about the current interpretation of these demands, beginning with an account of how present approaches are modified from those described and discussed in previous studies.

According to the HFEA's current Code of Practice the centre should refuse treatment only if it:

- a) Concludes that any child who may be born or any existing child of the family is likely to be at risk of significant harm or neglect, or
- b) Cannot obtain enough information to conclude that there is no significant risk.

In deciding whether to refuse treatment, the centre should:

- a) Take into account the views of all staff who have been involved with caring for the patient (and their partner if they have one), and
- b) Give the patient (and their partner if they have one) the opportunity to respond to the reason or reasons for refusal before the centre makes a final decision.

Assessing the potential risk posed to a child based on past or present patient behaviour or circumstances was the most concrete aspect of the assessment process. The HFEA welfare of the child form, as noted above, was widely used and the form reflects this 'risk assessment' character in its questions on past convictions for harming a child, social services involvement with existing children, the presence of 'violence or discord with the family environment', the presence of mental or physical illness or disability in the patient, the risk of transmissible or inheritable conditions, and the patient's behaviour with regard to alcohol or illegal drugs. This section of the report works through what emerged from the interviews about decisions and practices regarding excluding prospective patients from treatment. First we discuss staff accounts of the risk assessment process and its outcomes. Second we discuss evidence regarding actual exclusions including, in the light of issues raised by previous studies (Douglas 1993), the ways in which prospective patients might be excluded prior to coming through the clinic doors.

### 5.31 Convictions for harming a child

The HFEA form's first question asks the patient to declare whether they have any convictions for harming children, suggesting that the desire to filter out child abusers is at the centre of the welfare of the child assessment. It was evident from the interviews that the most clear-cut reason for refusing to treat, in the mind of clinic staff, was where patients had a conviction for harming a child.

Nine clinics reported experience of patients coming forward for treatment who either declared a conviction for harming a child or where information about a conviction emerged from other sources (for example, the patient's GP, an anonymous tip-off or, in one case, from the police):

*R: I can't remember ever seeing it for the first time on a form. I think we've had one or possibly two patients over the years where they've been on one of the registers and no, we won't treat...*

*I: And do you remember how you found that out?*

*R: I think the first...I can't remember them specifically...I don't think I've dealt with anybody directly in that situation but I remember it coming to our MDM years ago and I think the GP did disclose it in the original referral letter.*

*I: But it's extremely unusual?*

*R: In our experience, yeah. (Site 15, Doctor)*

However, because there are so few cases of such individuals seeking treatment, this focus for risk assessment and making judgements tended to take on the form of the spectre of the child abuser,

rather than experience of dealing with those with actual convictions. The view was commonly expressed that a 'real paedophile' would be unlikely to declare any convictions on an HFEA assessment form and may not even have been caught or convicted in the past:

*R: ...this whole process relies on the honesty of patients and...and then the knowledge of anybody else that you enquire from, so there are some people, I guess, who would argue that the whole process is pointless because you could hide the information so easily. Nobody's checking registered offenders and things like that...*

*I: ...with the example you gave, do you know whether with the patient's self-declaration (of a conviction), if that was the point at which it stopped or was there further investigation?*

*R: There was further investigation which was consented to by the patient..which was surprisingly honest to be honest. And it wasn't a blanket 'no' either. It was a case of, 'Look. We're not willing to treat you but we're willing to give you counselling. We're willing to investigate further. Speak to anybody professionally that you may have been talking to about these things', you know. But at the end of day the decision that we made as a group was that we didn't feel that it would be correct to treat that couple...You have to feel sorry for the partner, obviously.*

*I: ...who did you feel that you could pursue it with? Who did you go to? The police, or a CRB check?*

*R: It was the GP initially and then I think the person was seeing a psychiatrist as well...so it was reports from both if memory serves...and we don't get it very often...You know, I think it's once in 15 years. (Site 18, PR)*

In the few cases where an individual declared, or was found to have, a conviction for harming a child, the decision to deny treatment was not always as straightforward as this response suggests:

*R: ...[T]here was one actually about three months ago um...a convicted paedophile...he didn't get past the first appointment.*

*I: And how did you know he was a convicted paedophile?*

*R: The GP wrote it in the letter, which was really strange, because it was kind of a letter to say: 'I'm writing this, I don't expect you to proceed with the treatment because there are serious issues. He has only recently offended...'*

*I: But the patient saw that the GP had written this?*

*R: Yeah, but the couple had strongly requested a referral so they were seen and we were told it was a recent conviction...*

*I: ...did they get as far as doing this form [welfare of the child form] then?*

*R: Oh they did do the form.*

*I: And he wrote 'yes'? [To the question on the form concerning convictions for harming children]*

*R: I don't remember looking at the form afterwards, but they [receptionists] will know because our receptionists do it automatically [look at WOC form] when people check in for their first appointment.*

*I: And was that discussed or was it just so clear...*

*R: I only remember that case because we had our senior team meeting and a consultant that said 'Oh by the way I saw this chap this week and I've told him straight away we're not...he's not at any stage close to being considered for treatment'. (Site 13, Nurse)*

In other cases, when investigated further, there were often mitigating circumstances that made a 'blanket' refusal to treat inappropriate. Given that the need to screen out those with convictions for harming children has a such a high profile in the welfare of the child assessment process (it is the first question on the form) and is clearly at the forefront of the minds of staff, it is perhaps surprising that even patients with such convictions were not always greeted with an absolute refusal at the first stage. Decision-making about past convictions could be very complicated. In an example that predated the 2008 changes, the fact that a prospective male patient had a long-spent conviction for a sex offence was initially thought not to impose a barrier to treatment, but further consideration of the nature of his relationship with his current partner led to the clinic refusing to treat.

*R: We took on a couple where we were considering treatment with donated sperm and this particular couple – some time ago – the husband was quite a few years older than his wife; I think some 15 years older and he was honest with us from the moment he came with us and*

said, 'Look, I have...I do have a conviction in the past which might come up if you make any enquiry', and we, of course, asked for a...details on the conviction and he was a...Schedule 1 offender and when we went into the story deeply through our ethics committee, he was someone who had interfered with his younger sister...when he was a minor, yes...This is sort of 20 years later...when we now see this man. He said, 'Look, I'm being totally honest. I've never had a problem in my life. This was a difficult adolescence that I had. I realise this was totally wrong with my younger sister',...that all sounded very reasonable until someone pointed out that his new partner was the same age as his sister and some of the aspects of their relationship were very much brother/sisterly rather than husband and wife...So we discussed all this in the ethics committee to help us...He was open and honest about it. From the very beginning he said, 'This will come up. I would want you to know before you start'.

I: OK. And then the thoughts about the relationship came from the consultation?

R: Yes. Interviewing them. Yes. I mean I felt a little uneasy about it. We took legal advice. We went to our ethics committee and the ethics committee's advice was this is a Schedule 1 offender. This should not...this gentleman should not be treated. And we withheld treatment.

I: So that's sort of a straightforward refusal?

R: Yes. Straightforward refusal. (Site 5, Doctor 2)

The clinicians tended to give the impression that they were very reluctant to deny treatment without strong evidence that the patient would pose a risk to their prospective child. The difficulty in measuring such a risk, or proving that there was no risk, was apparent in their responses.

*...it was a sexual assault against an 18-month-old child, which went back to when he – the man – was maybe...was in his teens...This is him coming along 11 / 12 years later on with a partner...we made a decision probably two or three years ago not to go ahead with treatment but they...they've got another...a solicitor's letter that has come in and there was a whole issue around the time.. at the time about social services being involved and making an assessment of them but the big difficulty we have and you might pick this up later on, is that when you actually ask for a social services assessment, they – certainly locally – will not provide that until there's actually a pregnancy that's achieved...there can be social services involvement because of concern about a parent with a previous child that's been neglected or whatever...but the social services involvement will not happen until a pregnancy's been achieved...whereas in actual fact what we could do with is exactly that same assessment but prior to achieving a pregnancy. So in a way you're in a Catch 22... (Site 6, Doctor)*

There were divided views amongst staff as to whether a sex offender could be rehabilitated. In general, doctors seemed to be more willing to believe in the possibility of this than nurses and counsellors, perhaps because they were less involved than doctors in exploring further the individual circumstances of problem patients or this may reflect a more fundamental difference in the way staff who had been given different sorts of professional training consider patients:

*Well they can generally lie because it's all from patient information, so how useful it is, I don't know...it was a very interesting one a few years ago where the chap had been convicted...it was exposing himself to children, as I recall – not directly abusing – but exposing himself to children so therefore a risk and was on the register, but it was a spent offence from many years before. The clinician felt that...very compassionate idea that he felt that some sort of spent conviction, he'd done his kind of punishment and that we should consider but...and he was going to go on to treat but it was actually a member of nursing staff who kind of blew the whistle anonymously through an anonymous letter which was, you know, a worrying process that somebody has to do and there was a huge debate – ethics committee. My view was that...that child protection, child abuse or risk is not about doing your sentence, it's a life-long risk and that was a huge issue. It's a very...entirely different kind of offence and we need to acknowledge that. He...they erred on the side of caution – the ethics [committee] supported that – so they didn't receive treatment, which was sad in the sense of, you know, there was a couple and trying to rebuild their lives but he was specifically exposing himself to children and, you know, depending on the pathology, one could say that he could have gone on to do more of maybe things that we didn't know about. We had to look at only the offence but it was an offence against children, so...but he was open about it but we wouldn't have known about it if he hadn't been open about it...They contacted the GP and then the ethics committee wanted more information and I think he gave permission...I think he gave permission for*

*probation to be contacted but I don't think we got that far because ethics said, 'We're not happy about this'...it was more because of the conflict it was causing in the clinical team that they decided not to treat. (Site 4, Counsellor)*

Patient honesty was highly valued; where information came to light but was not declared by the patient, this was deemed more problematic than simply the fact of the conviction. There was a common feeling that patients with a conviction would be unlikely to declare it on the welfare of the child form. In this case, information about a patient came to the attention of the counsellor due to personal connections with social services.

*R: You are relying on patient honesty and the first question: 'Do you have any previous convictions relating to harming children?', well if you have, are you seriously going to put 'yes'?...you know pre the change in the welfare of the child bit...the GPs used to fill in the form, not that the GPs necessarily know everything about it and you could say that there are shed loads of people out there who go out procreating at will without thought or consequence who never have to fill in one of these forms, so why should our patients be any different? But what a waste of space really because I've never seen anybody who has filled in 'yes' on that and I would be very interested to know if anybody in the entire country has ever ticked 'yes' to that. My gut feeling would be no.*

*I: So have you had experience of information like that coming up in a different way?*

*R: Yeah, yeah...The information came to me from a social worker in [place name] who knew that a particular woman was going to be seeking infertility treatment and there was an ongoing massive investigation and court case going on with this particularly well-known very messy family...and she wanted us to be aware that this woman was going to come through for treatment quite imminently.*

*I: And the court case was to do with harming children?*

*R: Yeah it was a massive paedophile ring in [place name]*

*I: So what can you do with that kind of information in that example?*

*R: In that sort of example, I need the patient's name and when she was referred. I informed the doctors that this was ongoing, that we would need significant welfare of the child investigated information, that we would have to see the patients. As it was, the patient and her husband...I think actually she stabbed her husband so they split up...but we would have gone the distance because we would have said sort of 'right, ok, first thing we are doing is contacting social services' regardless of whatever they fill in on that, because the name is known to me and that was possibly sheer fluke you know. (Site 12, Counsellor)*

Discussion of convictions for harming children often led interviewees to raise cases where other convictions became a cause for concern. Convictions for other crimes could also lead to refusals.

*R: Last week I was seeing a guy who's coming with his wife to have treatment whilst he was in prison. He was in open prison and he will complete his sentence by the end of the year. Of course, we asked what was the sentencing connection for that very reason and incidentally, in this case, the guy was just employing illegal immigrants or something like that and he was helping them come into this country. That's why he got the sentence of four years.*

*I: And how do you follow that up, something like that? Because obviously there's nowhere on the form for those kinds of convictions, but is that just a matter of asking the patient?*

*R: Ask him, but he has papers. He produced a paper to show it.*

*I: And do you see that kind of thing as a welfare of the child issue?*

*R: If the guy is coming clean and giving us a reason that he was on the wrong side of the law but not in a way to affect directly the welfare of the child, then...the only bit that I felt obliged to do something about it, I said, 'Yes, you have still three or four months to go. It would be sensible to wait until you are out.' That's all.*

*I: And what about if there's a conviction for violence but it's nothing to do with a child, for example? Would that lead you to do anything?*

*R: I think we would need to do a little bit more work. A) we will insist that he sees a counsellor and B) we could write to the GP and ask if there is any additional information from social services that could give us as much information as possible.*

*I: And from your experience, is that quite a fruitful route? Does that work?*

*R: It does work sometimes and sometimes it becomes a pain when you'll find the GP say, 'I can't provide this', or you find the social services not particularly helpful. It does happen.*

*I: So do you find it's actually quite difficult to get information from social workers, for example?  
R: Not all the time. I don't want to be unfair to them, but occasionally it can be.  
I: Do you ever ask for CRB checks?  
R: I can't recall personally having been in that situation. No. (Site 7, Doctor 1)*

*R: We've also had convictions...I'm not sure specifically about harming children, but sexual convictions – things like that.  
I: And would that be an absolute barrier to treatment?  
R: You would certainly.. we would discuss it and I think we would have to know more details of the specific case before we turned anyone down, but...  
I: Do you know if CRB checks are ever asked for?  
R: Not as far as I'm aware. I don't think we have ever asked for CRB checks for patients.  
I: But probation officers might be consulted?  
R: Yeah. Yeah.  
I: But do you think those patients would have said 'yes' on this form?  
R: I think they would probably say 'no'.  
I: But would you be fairly confident that that kind of information would emerge?  
R: No. (Site 12, PR)*

*Well we do sometimes get things in there and yes, certainly, because one of the few people that we've turned down I saw was a guy who had a criminal conviction for violent crime. It had been a one-off, he'd served his time, he'd done all of that and.. and the problem then was getting an assessment of him to understand what the risk was of recurrence because he had a kind of...a pseudo-psychiatric background in that he'd been seen by a psychiatrist, he was never given a diagnosis, we've never treated, as such, and they discharged him but we had no understanding about what the risk then was of him being violent again and we tried to get information from various sources and got nothing at all and we ended up having to say, 'Well I'm sorry but we can't treat you because we can't get the support to say that it's OK.' So that wasn't for child things, it was just for...it was a violent crime with psychiatric background. (Site 15, Doctor)*

### **5.32 Social services involvement with the family**

Another indicator of high risk was previous social services involvement with existing children (the second question on the HFEA form). This was more common than experience of convictions, with half of the interviewees describing experiences of patients with social services involvement. Again, this routinely generated further investigation, but would not necessarily preclude the provision of treatment. Because individual circumstances were likely to be far more complex than might be anticipated and because refusals were so unusual, there are no 'typical' cases.

*We have had people tell us that...it's usually the chap, that he's had a child in his previous relationship and that child might have then come into care, but then again we just have them in to explain the situation...It would be followed up, they would explain it but we would always then ask their GP...I mean I think it's kind of limited which people you can ask, but if there's any issues at all, the patient is always the first one we discuss it with and then we'll ask for their communication consent to feed out to other people...and we would ask them 'well who was involved in this, who do you think may be able to supply us with information', and then they'll give us that consent to communicate because I think it's important that they know why we're doing it and where we are with it, and why we're not rushing them straight through. (Site 13, Nurse)*

*R: There have been one or two where children, existing children, have been taken into care or have been under some kind of care order and they've maybe...it's a new relationship but one of the parents has had children who've been in care for some reason. I would certainly be asked to investigate all that kind of thing.  
I: And is that something that would come up via the form?  
R: Well I guess if somebody ticked 'yes', it would wouldn't it?...But again I don't know whether people would tick 'yes'.  
I: In the examples that you gave just then, would you know if they would pre-date this current system so might you have had information about that from the GP referral?*

*R: Yes I think so but I don't recollect having seen anybody since the new measures came up. I don't recollect having seen anyone about child protection issues. (Site 10, Counsellor)*

*R: What we've done is we've got [Counsellor] quite heavily involved... We ask the couple's permission to write to the GP to get more information and I have to say the majority of times we've done that – it's not many – actually the majority of times things have turned out to be OK... But there have been one or two cases where we've... where we've had to say to people, 'We're really sorry. We think there's an issue. I'm afraid we're not happy to be involved'... But God, it's a tiny number.*

*I: And what about actual convictions of harming children? Have you ever come across that?*

*R: Wow! Not that I can recall.*

*I: And what do you think of the fact that the form asks people to tick 'yes' or 'no' to that?*

*R: I think it's a reasonable question. If you believe in the act and you want to apply legally the act as one is supposed to then I think it's a reasonable question.*

*I: And can you imagine people saying 'yes'? I mean do you feel that patients in your less formal way of doing this [the clinic did not use a WOC form at all], would people tell you that they had...?*

*R: No. I think people tell you what they think you need to know. And we've seen that with smoking. You know, what's happened with smoking now is the NHS have said, 'We will not fund IVF for smokers', so nobody smokes anymore. (Site 17, PR)*

Follow-up in such cases usually entailed making contact with the social workers involved in the case and contacting the patient's GP. Patients were also often required to speak to the clinic counsellor either for an explicit assessment session or for support during the process of investigation.

### **5.33 Violence in the family**

A very small number of patients were reported to have declared either their own, or a partner's conviction for domestic violence on the WOC form or during early consultations. Such declarations were regarded as necessitating further investigation either by a doctor or by the counsellor. In a few cases, violence between partners emerged during treatment, for example from bruises evident on the female patient's body or from the patient requesting a halt to treatment because of an attack by a partner. For treatment to resume in these cases, the couple would usually be required to see the counsellor. Revelations of abuse emerging from supportive, non-assessment counselling, were generally thought to require the counsellor to break confidentiality (with the consent of the patient) to inform the rest of the team as a welfare of the child concern.

*R: I said 'no way are we going to treat, no way'. It didn't go through the team but I said, 'well this is exactly what's going to happen'.*

*I: And how did you know about this?*

*R: She told me.*

*I: Because she was coming to counselling anyway?*

*R: Yes she was. if they're not sure about treatment somebody will sort of say 'oh go and see [name of counsellor], she'll sort them out', and she didn't quite understand treatment and then I started with... these are the limits of, this is what counselling is, these are the limits of confidentiality and it went through... we'd sat there sort of got to the end of session... first session and she said 'if my boyfriend beats me up, what difference does that make?' so I said 'well pretty damn significant', so on the second session we sat and talked about all of that and she said 'I wish I hadn't have told you'. I said 'yeah but you did' and having told me that now and she showed me bruises as well because it was ongoing and I said well... I continued to see her while we sorted some of the stuff out but I said 'you're not going to get treated and I will write to your GP'. (Site 12, Counsellor)*

Sources of information could sometimes be less reliable than self-declaration – anonymous 'tip-offs' were cited a couple of times, once in the case of a patient accused of accessing child pornography and another where an alleged history of domestic violence was brought to light by a former partner of a prospective patient. Such incidents were felt to place clinics under an obligation to investigate further, while recognising that the sources could have malicious intent:



*R: We've got an issue going on at the minute where they've actually said 'no' to everything [on the WOC form] but then we've had an ex-partner of one of the patients actually write a letter to say there's a long history of domestic violence and they only want treatment because they want a boy, that kind of thing, so that's kind of being investigated at the moment where the consultant has written letters out to their GP to try and get a clearer picture.*

*I: And in those circumstances, does the consultant have to talk to the patient first thing so that they know this?*

*R: Yes, they were brought back to the clinic to say that we've received this information...obviously we don't know whether it's been sent in with malice or whatever but we have to investigate it. (Site 13, Nurse)*

### **5.34 Drug users and heavy drinkers**

Almost all of the clinics had experienced patients with either a history of drug or alcohol problems or with concerns about their current use. Patients with drug and alcohol problems were considered for treatment provided they were not using alcohol or illegal drugs at the time of seeking treatment. In such cases, welfare of the child concerns were often couched in terms of the impact of drugs and alcohol on the patient's chances of conceiving either naturally or with treatment. Cases of refusal could therefore be made on the grounds that treatment would not be effective unless excessive use of alcohol and drugs were ceased, rather than explicitly on welfare of the child grounds:

*I mean the drugs and alcohol; like I say, we've...we've had a situation like that before where they may be on social recreational drugs and that clearly affects their sperm and also their fertility and really, counselling them on that, you know...try and get them to stop all that kind of stuff beforehand because it does effect the sperm production. (Site 9, Embryologist)*

However, current use of drugs or excessive consumption of alcohol was not a considered an absolute barrier to treatment; rather it was a reason for the deferral of treatment and the seeking of further information from the GP and any specialists involved. One of the rationales for this way of thinking about illegal drug use was that it is relatively normal in wider society and therefore it would be unfair to impose higher standards of behaviour on infertile patients than on individuals able to conceive naturally:

*I would think it's more common. I mean just because it's more common, like in, you know, in the population, isn't it but it, I mean, you know, it depends to what extent that drug and alcohol problem is, I suppose.. if there is an issue then obviously they need to see the consultant, you know, in the clinic and sort of get the root of it and then obviously further investigations whether it's writing to a psychiatrist, whether it's writing to a GP, whether, you know, or social worker or whatever needs to be done to sort of, you know, get a bit more further information. (Site 13, Embryologist)*

*Off the top of my head we've had more drug-related problems than alcohol-related problems. Again, lots of those are flagged to us in GP letters. We've had one or two that we've sort of brought up and we've looked into it. I can remember one or two cases where we said to people, 'Go away and get this sorted out and then come back and see us'...I mean no proof but there'd be concerns about it and so we said to people, 'Look, we're very happy to help but you've got to go away, get this sorted and come back to us when it's sorted'... There will be one or two situations where there would be a direct medical impact, so opiate abuse and cocaine abuse would be specific issues in terms of the welfare of the foetus so that would be very real, very medical and very easy to make a decision on. What would be a little bit more difficult would be if you felt there was some environmental context, so the couple would be pissed and therefore not able to look after the child. That would be more subtle and probably a little bit more difficult to make a judgement on, particularly if it was the male that was involved in that activity. Have we had any scenarios like that? I'm not sure if we've ever turned down a situation because of a male pattern of behaviour but these things are much difficult because it's not infrequent for us to offer treatment to couples without me never having met the bloke. (Site 17, PR)*

The GP was usually regarded as a good source of further information:

*R: Well we would check with their GP and whoever has been caring for them for those problems and decide whether they're fit enough to, you know, to be able to have children and have a child.*

*I: Is that something where the potential father is as much under consideration as the mother?*

*R: Yeah, yeah, yeah. Both. (Site 1, Embryologist)*

Information about drug use tended to come out in the patient's medical history rather than on the welfare of the child form. It was felt by some interviewees that patients were more honest in a medical assessment, which was not seen as having an 'agenda' than on the welfare of the child form:

*I: When it comes to drug or alcohol problems, would you expect a patient to tick 'yes' to that if there was an issue, or would it be something that comes up when you take their medical history?*

*R: Long before they would get to fill this form [WOC form] in, you know, I would have asked them – both of them – 'Do you smoke? Do you drink any alcohol? How much do you drink? Do you take any social drugs?' So that kind of conversation will have happened months before this... So we will already have some unbiased or independent information... not independent but I'd ask those questions in the first place, but I guess there was no agenda. It was just, you know, I'm asking you a question, you give me the answer. I always find it quite surprising how honest people are about those questions. They don't hold back and if I say, 'Take any social drugs?' I mean some people say, 'Oooh. Certainly not,' and others will say, 'A bit of marijuana. A bit of this. A bit of that.' You know, 'Still?', 'Yeah, a bit'... so enough people answer those questions in the positive to make you think that I'm probably getting a fairly honest response to them... And so then you would know what the issues were and you would then be expecting them to tick 'yes' if that was going to be the case. I mean those situations aren't terribly common... you'd then be aware so if they said 'no' you'd think well don't forget that you've got these things here.*

*I: So have you ever had to pursue that by speaking to others, like going back to the GP or to any kind of drug treatment?*

*R: We've had... not in this current one but in the past we've had people who were still fairly active drug users and you would... you know, told that, 'Until you come to an end of doing this we're not going to treat you... we had the facts and we said, 'Well...' you know, 'these are our criteria for treating people and we can't do it until you're finished'. 'OK'... our welfare of the child assessment in the past would have gone on before they came to see us, so we might have not seen them if they were... if there was a major issue and there was a major drug problem, so we would have said, 'You can't come through the door'. Now... the process... the barrier happens at the time of decision for a regulated treatment. (Site 11, Doctor 3)*

Others thought that a patient with drug or alcohol problems would not get as far as having a welfare of the child assessment as they would be filtered out at an earlier stage of referral or investigation:

*R: I think that we've screened quite a lot of that before they actually get to this point, so if they have had drug or alcohol problems then they would have... it would have been discussed or they would have actually been, you know, 'you're not going to be suitable for the clinic if that is an issue'... you know, 'if you continue to do that'.*

*I: And would that tend to come out in their talk with the doctor?*

*R: Yeah. (Site 11, Nurse)*

### **5.35 Mental or physical health**

The most commonly reported reason for welfare of the child concerns was a patient's mental or physical health. However, as in the examples detailed above, each patient was described as being assessed on their individual circumstances and there seemed to be a strong presumption to provide treatment unless causes of concern were irresolvable through further investigation. Concerns for the welfare of the future child were often secondary or intrinsically connected to, concerns about the wellbeing of the patient and their ability to cope with treatment or pregnancy. These were usually more immediate concerns than concerns about the patient's ability to cope with parenthood.

## Depression and mental illness

All clinics had treated patients who had experienced depression. There was a consensus that patients tended to raise this themselves, but often did not declare it on the HFEA WOC form, as they did not consider depression to constitute a 'mental illness'. Where a patient's GPs had been made aware of their depression or where drugs had been prescribed, this would be written in their medical history. There was widespread recognition amongst clinic staff that mild or moderate depression, including that requiring medication, was common across the general population but could also be strongly associated with the experience of fertility problems. This kind of 'everyday' depression was not seen as a barrier to treatment, although some clinics would recommend that patients saw the counsellor prior to, or during, treatment for support, and in some cases, for further assessment.

*Depression is depression. That to me is not a psychiatric illness, it's a condition that most of us are going to suffer from at some point in our lives...If you look at infertility, anyone that's had infertility for two years ...is likely to have a low level depression...if it's severe behavior-changing depression, then yeah, I want to know what they're doing about it, how they're coping with it, who they see, where they get support from and you wouldn't even begin to start treatment until they've got some coping skills in place. (Site 12, Counsellor)*

Because the use of antidepressants was so common amongst patients, one of the clinics was modifying their welfare of the child form to ask questions about the type and dosage of antidepressants being taken by prospective patients, with different protocols and pathways for dealing with lower or higher dosage medication:

*I would say that you get an awful lot of people who will have experienced depression at some point. It may not necessarily be having ongoing treatment for depression, but certainly maybe in their past history...I would say that that comes up fairly regularly...I think this is why we're changing the form at the moment – I think whereas previously if anybody was on medication for depression, it was an automatic referral to the counselling team and at the moment what [Counsellor] is trying to do is alter the form so that there is a little bit more guidance around what are appropriate referrals and what aren't. So previously it would have been an automatic referral. Whereas if somebody had had a bereavement five years before and had a short course of antidepressants but there's been nothing since then, although they would be more than happy to offer support it wouldn't necessarily be a referral. (Site 14, Nurse)*

Despite the common view that depression is normalised and therefore that patients with depression are prepared to be fairly open about their condition, one counsellor thought that patients might worry about the consequences of their history being known.

*Yeah, I think patients are concerned. Patients are very concerned about things like history of depression and how that may follow on. They're more concerned when they come potentially to the end of treatment if they're going to look at adoption and it comes up for me for couples. I notice some couples will carry on with fertility treatment where they know that their profile is lousy and that they've been told it's very unlikely to work because they're afraid of then having to be assessed for adoption because there's perhaps a history of depression. (Site 4, Counsellor)*

A strong distinction was made between depression and serious mental illness: patients with a history of mental illness were felt rarely to present for treatment either because of self-selection or because of prior stages of filtration in the referral system.

*You'll occasionally come across people who when you take their drug history in their primary visit will admit to being on some sort of antidepressant medicine – things like that – but we would...generally, we're not going to see people who would be categorised as being schizophrenic or treated schizophrenics or psychotic-type people, so it will be the much milder range of things so no, true psychiatric disorders are quite limited, really. (Site 11, Doctor 3)*

*I mean depression to me is every man's disease um...schizophrenia or bipolar difficult again. For starters there's the fact that it's you know, it's genetically linked...we would ask for psychiatric report...I would want to talk to them a lot about the impact of having children, how*

*they manage their illness, what the risks are to the child, sort of what about you know added stress...we have one woman at the moment...I mean we won't touch her with a barge pole. She hears voices from the TV and she has a son and I have written to the GP with some concerns about the son and no, we won't treat her but at the moment she sort of enquiring about treatment but I know that we won't do it. (Site 12, Counsellor)*

Cases were also described of mental health problems emerging or worsening during treatment and becoming of concern to staff:

*R: I think people, we would generally know if they're on antidepressants or some sort of medication for a psychiatric illness. There are other people who as you get to know them, you begin to wonder if they might have issues which they need to seek advice about so they're in the main spectrum, but they're just teetering on the edge and that's often tricky to know whether it is the stress of treatment or whether they have that tendency anyway and treatment might make it worse. But without sounding pompous, the team here are quite stable and been here for a very long time and there is very good communication, so if someone...for example, a nurse were to scan somebody and think oh, this is a bit strange, then they might come out and discuss it with a member of the nursing team to say, 'Could you scan this woman next time? I'm a bit uncertain'. And if we have concerns, we would speak to the consultant again...we have a girl with anorexia who had to reach a certain BMI to be fit for treatment. She was showing very bizarre behaviour but, you know, not wildly outrageous, but just a bit strange and I became aware when I scanned her that maybe she was losing weight again and I felt I had to kind of ask her about it and we...we kind of do; we will challenge that. And she was extremely angry about it but, you know, she was doing the whole bulky jumper thing...so I would have approached our consultant to say, 'I'm worried about this patient. Can you see her again?' And we would talk to her again about, 'You've got to be fit and healthy to be pregnant and this weight is not good'.*

*I: Presumably she'd obviously already completed the welfare of the child form?*

*R: Yes.*

*I: That was signed off, so when you're raising that as an issue, in your mind, is there a kind of welfare of the child issue?*

*R: Yes. Totally. It's about that...It's about looking after this woman who's drifted off. Why is that? Is there something bigger going on that might impact on a child and then there is the issue that treatment might not be so successful because she's lost lots of weight, so you're dealing with a complexity, but the welfare of any child, it's a phrase you can't use without thinking about, really...both our consultants are also obstetricians and gynaecologists, so they're not just fertility doctors. It's that whole thing and one of my team is a midwife in a different setting and another girl is a gynae nurse who's come here and we've got all our own life experiences. (Site 10, Nurse)*

There was a desire for clear guidance from psychiatric or psychological professionals with expert knowledge of a patient's particular condition:

*What we've done there is we have written to the psychiatrist. We write to the psychiatrist to say, 'This is the situation', and essentially we kind of slightly pass the buck to the psychiatrist and say, 'Look, we're having to make this assessment. Is there anything that you can add either positively or negatively to say there could be a concern here?' and usually psychiatrists have been pretty good. Usually they will come out and say, 'It's all fine. Their medication is well under control. They're stable. I would definitely support this couple's application', and that's made us a bit easier. We've had psychiatric histories quite a lot. I can't remember one that we didn't proceed with...but in each case we would have confirmed support from the psychiatrist. (Site 17, PR)*

In this case, the doctor was frustrated by the unwillingness of psychiatrists to provide a decisive opinion on whether a patient with a spent conviction for violent crime had a psychiatric condition that would make him likely to reoffend:

*They clearly were worried that there was something going on with him with his brain that...and that, perhaps, makes it more risky, I suppose, although, you know, a spent violent crime, who knows whether they're likely to do it again? People who tend to be violent might be again, I*

*guess, but we get reformed characters too, so it's difficult, but in that particular situation, that was the bit that tipped the balance. We couldn't get the report from anybody...from discussing it with the couple I knew who he'd seen and which consultant had been involved, which psychiatrist had been involved and I wrote to them and got very little useful information back at all, unfortunately...They sort of said, 'Oh well we didn't have diagnosis. We didn't treat him', and you kind of say, 'Well that's fine. So you think he's normal then?' but what they then turned round and said is, 'I'm not qualified to comment on his ability to parent' and so they just opted out... (Site 15, Doctor)*

### Serious and chronic illness

Most clinics had some experience of treating patients who were suffering from a serious illness. Chronic, ongoing conditions such as diabetes and epilepsy were mentioned at a number of clinics. These were discussed as issues for the wellbeing of the patient, the wellbeing of any existing children and the wellbeing of the future child. Some patients were refused treatment on the basis that their health was judged to be further imperilled by fertility treatment; however, the implications of treatment for people with such conditions varied from patient to patient:

*We have had one case, actually, with a lady with diabetes. That one went to the ethics committee because she had very...quite severe diabetes and so the full sort of prognosis was obtained. I think we've treated one case before which had a rare chromosome abnormality, which would potentially affect her life expectancy, and again they were cases that have gone to ethics committee. (Site 5, Embryologist)*

Patients with life-threatening illnesses would be the subject of much discussion within clinics, with expert opinion sought from other medical specialists. There was a desire for clarity and decisiveness from such specialists.

*There was another woman who had a metal heart valve who was on anticoagulants and we again, got her to be seen by the obstetric physicians before we could treat them so I guess those were quite physical things, as opposed to psychological things but we chose to have them screened and reviewed for their views about their physical health before they encountered a problem...if they had said, 'This is not an option', then we would have said, 'Thank you very much. That's the advice we will take and we won't treat them'. (Site 11, Doctor 3)*

There was some frustration that the patient's specialist consultant was sometimes unwilling to offer a judgement on whether or not to treat, however, this was more from the point of view of the welfare of the patient than the welfare of the child. In this case, a clinic had decided to act against the advice of its ethics committee because staff felt the risks to patient's health from conceiving were unacceptably high:

*I'm aware of having gone against it once and they knew I would and that was a case where it would be...it was going to be serious risk to the patient's life if she were to conceive and the ethics committee argued that it was her choice and my view was well, if she was going...this is going to sound terrible; if she were going to kill herself, that would be her choice but she couldn't ask us to do it for her and my concern is then for... apart from the fact she had an existing child, who clearly.. whose welfare was a major issue, then we have all the staff at the clinic who would have been involved had she died because we had agreed to treat her so we didn't treat her but...they did...I think if we took it to the current ethics committee, they would have agreed with our course of action but...the then ethics committee felt it was the patient's choice and we said, 'We feel yes, there is an element of patient choice but it is also our choice and we're saying no, we don't want to put her to this risk'...and so they said the risk in pregnancy is... close to 50 / 50 that she will either die or be...her life will be seriously impaired in the sense that it wasn't already so we said no and her...her partner went, 'Yes!. It was a huge relief, I think, for him. (Site 20, PR)*

Where the patient was thought to be well enough to bear treatment and pregnancy, from a welfare of the child perspective, the concern was with the patient either becoming more ill or dying during the

child's early years. There were sometimes interesting differences in the way illness in male and female patients was discussed:

*R: We've got a man for example at the moment who's having dialysis – has got severe renal problems and he is awaiting a kidney transplant. He may get one and may live a long time but the probability is with that sort of illness that he may not live until they [the prospective children] are 18 and in that situation, I saw them, [the counsellor] saw them and we talked very candidly and explained that you know, this is your situation and you might be unwell when the baby is young or you might even die and then we look at what other social support the woman has, after all, we treat single women. So he is going through treatment now.*

*I: And how does your assessment of a mother versus a father in those scenarios work? I mean, presumably with a woman obviously, you've got the health implications of the pregnancy itself...*

*R: That's the biggest thing really, because most conditions that have a big impact on her life expectancy would have a big concern for her pregnancy but if, for example, we thought that she's fine now but her condition might deteriorate, I don't know, but I think that somehow is a bit more worrying if the mother's going to be either unwell when the baby is a toddler, or there's a possibility that the child may not, you know, that she may not live long enough for the child to reach 18 or whatever, so we would take that more seriously I think than most people would. But no absolutes, obviously...I think it's a bit, I think you know maybe it's sexism on my part but I think the relationship between a child and the mother is slightly, in a sense, slightly different to that of a father and a child I think. (Site 1, PR)*

The difference between mothers and fathers also came through in the consideration of the welfare of the child in cases of fertility preservation. A number of the clinics situated in major hospitals had close relationships with oncology departments and regularly saw male and female patients who were seeking fertility preservation prior to radiotherapy or chemotherapy, some of whom went on to have licensed fertility treatment after recovery. Many of the clinics stored sperm, eggs or embryos for oncology patients, with collection often being conducted in a hurry between diagnosis and the commencement of treatment:

*The oncologist is banging on the door to give them chemotherapy. Quite a stressful scenario, that. And actually, for me, that really is genuinely one of the real toughies. You do want to take welfare of the child issues into play. If you're looking at a one-parent family, now again, would you deny somebody treatment just because one of the parents might die? So it's very easy for the bloke, so if we had blokes coming in that were terminal, we always felt more comfortable. Again, this is completely prejudicial but we'd always feel more comfortable if the woman was going to be healthy and happy, she was going to be pregnant and be the mum to bring up the kids. We've done lots of cases of posthumous treatment where we've had prior preserved sperm. Now where we started to get more difficult was when the woman came in quite sick and may die, and again, that was our own prejudiced thinking, well she's the woman. She must be the mother and the primary care lies with her which, of course, is not necessarily the case at all and so we've become a little bit more liberal in that approach now by saying, 'Actually, do you know what...?' Where having a one parent family is not an ideal compared to the child not being born at all, as opposed to coming into a one-parent family where it would be loved etc and we felt more comfortable doing that. (Site 17, PR)*

However, not all oncology patients were required to undergo the welfare of the child assessment at the stage of gamete collection:

*We do see a lot of oncology patients, so we will sometimes do the welfare of the child forms for those patients. I think there was a time when we didn't do them but some of them will get done especially if they're looking to consider treatment...It depends, because, there can be a long gap between seeing those patients and then them coming for treatment. (Site 12, PR)*

### **5.36 Disability**

Patients with disabilities also seemed to be considered for treatment on a case by case basis, with consideration being given to the patient's particular physical or medical condition, as well as their social circumstances. Expert medical opinion was often sought on the potential risks to the patient

from pregnancy and labour. In most cases, the physical wellbeing of the prospective mother was tightly bound up with the future wellbeing of the child. GPs, medical specialists and social services were approached to provide further information about the risks of treatment and possible pregnancy for the patient as well as their capacity to care for a child:

*We've had a lot of paraplegics. We've had achondroplastic dwarfs. We've had deaf people. I'm not sure if we've had any blind people. We've had partially-sighted people...I would say what we do is we get hold of the patient's doctor. We have turned down two cases but that was more...it wasn't welfare of the child issues, it was, 'the treatment or the pregnancy might kill you' and I can recall that in two cases...for medical reasons but again, not welfare of the child; specifically treatment-related risks to the person's health. (Site 17, PR)*

Another clinician thought that difficult cases where the patient's welfare was potentially threatened by fertility treatment would be filtered out at an earlier stage, presumably by the patient's own specialist clinician or by investigations during the gynaecological and infertility referral process.

*You know, disabilities that would impair your ability to have a child or survive much afterwards, they tend to get screened out through the whole process...you know, you almost don't have to play the...welfare of the child card. It's kind of a, 'in what world is this a good idea? Type of card, you know'. A good example might be, well, women with certain disorders who might die during childbirth. Of course that's a welfare of the child issue, but it's also a patient issue, isn't it? You know, if you're going to die that's not...you didn't come here to die so that you could give birth to a child; you came here to have a child and survive and the child survive. So a lot of that stuff, although we might call it welfare of the child, it's...it's welfare of the patient primarily. (Site 8, PR)*

Consideration was given to the patient's capacity to cope physically with raising a child. A key issue in assessing disabled or ill patients was the degree of support available from a partner or from other family members:

*R: Disabilities, as such, we don't really see them as a major issue because we don't come across the situation where both partners are disabled. So if one partner happened to be disabled that we can see that the other partner has considered all these issues and they are supported by family and they can look after the child.*

*I: And how do you establish that support? Is that through counselling?*

*R: We ask them and also via the counselling.*

*I: And is there anywhere else that you would go for further information?*

*R: If we didn't have a complete picture then we write to the GP and we write to social services. (Site 7, Doctor 1)*

*R: We also have a very seriously disabled woman...who we treated and so it's very evident in the letter of referral and then when they arrived that that was going to be hard for that family.*

*I: And how would that be pursued as a welfare of the child issue?*

*R: Probably the same we would anybody, that there would be a very frank discussion about this is going to be very hard for you to manage. But the seriously disabled woman had a very, very fit and healthy partner and they already had a child and...I'm not suggesting they just sort of walked in here and an hour later they went out done and dusted. There was a similar process...meeting our counsellor, a report, a team meeting and a decision and I think we did treat them. (Site 10, Nurse)*

In the case of single, disabled women, this made their chances of treatment being agreed to more slim. In one case, a single, disabled woman was provided with treatment once it was determined that her family were supportive and she had the financial resources to provide adapted housing to enable her to care for a child. In some cases it was thought to be very hard to judge the capacity of disabled patients to care for a future child, especially when further information from social services or medical specialists was not forthcoming or was not definitive.

*A couple who were... functioned as a couple but were both quite significantly disabled to the degree that they kind of look after each other and they, similarly, could potentially conceive on their own although with some difficulty and they certainly won't need to go...very unlikely to*

*get down to the route of any licensed treatment so, you know, this is irrelevant really but... but I'm reluctant to give them the help that they need because I'm concerned that actually they'll have a baby and they won't know what to do with it. So they're involved with social services so I wrote to social services and I said, 'Can you tell me that this couple in their home are going to actually be...and that's to do with physical things as much as anything and they wrote back and said, 'Well it's not our remit. We can tell you what we've done but they won't tell me anything about whether or not they think they could manage a child in their house...I just think that's really disappointing. I think it's not fair being the couple at all because my...my answer to that's going to be, 'Well sorry. I'm not helping because I don't know that you can manage.' I can't go to their home and see whether it's OK. You know, will they get or have they got...will they get the support? I find it frustrating, the social services link, I have to say, for pre-conception concerns. (Site 15, Doctor)*

Disability sometimes crossed over into serious illness and in such cases, the implications for the patients, the potential child and any existing children were assessed.

*If they say they've got a physical condition, you know, obviously they need to be assessed to see whether they're actually capable of caring for and having a child. We have had people, who've been, you know, obviously in wheelchairs and things like that...there was another lady who had one of those conditions that means she's getting gradually worse and she'd already got children and it was whether she was using her children as carers for any unborn child and there was a lot of issues about that. The GP got involved with that and everybody got involved with that and there was a lot of meetings and discussions about whether we should be allowing her to have fertility treatment and in the end it was allowed to go ahead and she didn't get pregnant, so... (Site 13, Embryologist)*

In this response we can also see another concern about disabled patients: that the child might end up shouldering a burden of care for the parent.

*.... what I don't want to make is a whole lot of child carers and, you know, you hear about them a lot and the kind of pressures that are on teenage kids to look after their disabled parents. I'd be very sad if that was what we were making by helping these folk, but at the same time, you know, we're only helping what otherwise might have been a natural process and might have parented anyway. They're the ones that I struggle most with. I don't want to be judgemental. I want to help them, but I don't have.. we don't have the tools to make those judgements very well. (Site 15, Doctor)*



## 5.4 Exclusions and refusals

### 5.41 Overview

The study aimed to assess the extent to which the risk assessment process led to actual exclusions from treatment. In order to find out about this we asked all respondents how many cases of welfare concern might arise in a year, and how many refusals to treat there might be in a year. It became clear early in the fieldwork that a) few clinics record such data in one place, and b) the numbers of refusals are very small. The information was therefore gathered through the interviews, with all responses from each clinic checked against one another to gain clinic figures.

Most of the clinics put at 'under five' the number of cases of welfare concerns in a year; however, three clinics indicated that they see between five and 10 cases a year where welfare concerns are been raised, and two said between 10 and 15 per year. One clinic, atypically, said 100-150 cases a year were subject to further investigation because of welfare of the child concerns (reporting, however, that less than five refusals a year resulted):

*I: Obviously it's low compared to the number of patients and then so you, if you say to one a week, then over a year you're talking about thirty to forty cases of concern, where there's something that's raised about the welfare of the child?*

*R: Oh no, much more than that!*

*I: More than that? Oh really...*

*R: If we say we have fifty MDTs a year, we might sometimes have as many as four or five [at each].*

*I: Really?*

*R: But sometimes only one or two, so an average of three, that might be a hundred to a hundred and fifty cases we will consider a year. (Site 1, PR)*

Most 'welfare concerns' were considered to be minor concerns that could be resolved by a little more information being sought, most often from the patients themselves, the patient's GP, or from a medical specialist. Hence, the overall picture is of the co-existence of a 'presumption to treat' with hundreds of treatment cycles per year at each clinic and typically a very small number of serious welfare concerns, with a general view at the same time that WOC assessments are an important part of the clinic's work.

Number of cases of welfare of the child concern in a year	Number of clinics and clinic size (by annual number of cycles of IVF and ICSI)
0-5	11 clinics (4=< 500 cycles, 5=<1000 cycles and 2=1500-2000 cycles)
5-10	4 clinics (1=<500 cycles, 2=800-1100 cycles, 1=1800 cycles)
10-15	3 clinics (1=400 cycles, 1=600 cycles and 1=730 cycles)
30-60	2 clinics (2=2000-2500 cycles)

Reasons for concern	Number of clinics reporting cases
Mental illness (including depression)	All
Illness: transmissible or inherited	All
Drugs/alcohol	All
Physical illness or disability	All
Violence in the family environment	10
Convictions for harming children	11

Where issues considered to be 'welfare of the child concerns' were raised, treatment could not be granted until further information about the patient's current or previous medical or social circumstances had been obtained to rule out risk, with the following describing the typical approach identified:

*...so we don't really refuse many people because I think we will investigate, we'll get all the evidence and then depending what it was, we would just try to support them as much as possible and see how we can treat them. (Site 13, Nurse)*

*I think the way we work is there's a presumption to treat and we give...we have to give the patient as much chance as we can to put their sort of side across, if that makes sense? But there...but there are occasions when we do turn down, so it's not a kind of like oh yes...obviously if something is found...there are occasions we turn down but it probably is only one or two a year, I would say. (Site 6, Embryologist)*

Further investigation was undertaken with a view to providing evidence that treatment could proceed. Sources of further information were most commonly:

- a) The patients themselves (patient consent is required for clinics to pursue further information from third parties);
- b) The patient's GP, through a letter;
- c) A medical specialist responsible for treating the patient's particular medical condition, including psychiatrists or community psychiatric nurses;
- d) The clinic counsellor, who was sometimes asked to conduct an assessment session with the patient to gather further information;
- e) Social services, where the patient had indicated that existing children had been subject to their attention or where a disabled patient, for example, had social care needs;
- f) Probation officers, CRB check or court records for cases of serious criminal behaviour (usually violent crime);
- g) Further discussion at a clinic multi-disciplinary team meeting;
- h) Drug or alcohol specialist, most often if the patient had previous involvement with drugs services. Occasionally, patients were referred to such services for treatment as a condition of fertility treatment being considered;
- i) In a very small number of clinics, independent social workers were occasionally called upon to make a fresh assessment of the patient.

Within the clinics, follow-up of welfare concern cases could be pursued by nurses, counsellors or doctors, but doctors usually saw patients to explain the reasons for further investigation. Most clinics held routine multi-disciplinary team meetings at which welfare of the child cases might be discussed. Cases considered very serious might also be referred to a clinic or hospital ethics committee.

Seven clinics said **refusals to treat** were so rare they would estimate that in an average year there would be none, two clinics said refusals happened only once every couple of years, eight clinics said one to two refusals per year was usual, two clinics said three to four and another said over seven cases might be refused in a year on welfare of the child grounds. All staff had examples of 'extreme cases', but these were often drawn from a number of years back or from cases staff had heard about but had not been directly involved in themselves. The rarity of refusals also meant that there were no 'typical' cases: all were, by their nature, complex and highly idiosyncratic.

Number of refusals to treat per year on welfare of the child grounds	Number of clinics
0	7
<1	2
1-2	8
3-4	2
7	1

**Deferrals of treatment** might be an outcome rather than a refusal to treat:

*I: So the one that was refused you think was the alcohol...*

*R: Alcohol-related, yes, as far as I know. Yeah.*

*I: ...was that a refusal to treat or a kind of deferral?*

*R: Defer. More of deferral, really. More of a deferral; go away, try and sort yourself out, basically. Do a few more sperm samples for us, you know, see if things improve. You know, that kind of thing rather than...not just a flat...I don't think they would completely...flat refuse someone, I think it's a case of explaining why this isn't a... the right time to help with a child and see if you can sort that situation out rather than just kicking someone out the door. (Site 6, Nurse)*

*R: ...we've had a couple who were very abusive to one of...member of staff – very abusive – and we brought them in for a discussion and it became very clear early on in the discussion that the issue wasn't with us at all; it was with their hospital and they thought we were part of the...other organisation, so I mean it was quite clear that they did have issues to be concerned about but her husband was particularly out of order so he apologised to the member of staff that he threatened basically and it...we resolved the issue.*

*I: And do you see that as having a welfare implication, or is it something to do with, you know, what you expect from patients and their behaviour?*

*R: Oh, we do expect reasonable behaviour from patients but if we saw that that was affecting, you know, a relationship between the couple then we would probably want to investigate that further and obviously you've got evidence of recurrent issues. We have had one chap about five or ten years ago who we sent off to anger management...a course...for a course which we...they had a look and then we'd...we got them through.*

*I: ...were they receiving treatment in that time, or did you defer treatment?*

*R: We deferred treatment while he went through his anger management course. But again, they recognised that there was an issue.*

*I: And did you...was that done on the basis of a kind welfare ground, or because you felt...*

*R: Yes, it was on welfare grounds. Yes. Because...and this lady actually expressed a concern that her husband had an uncontrollable temper.*

*I: OK. And did you end up treating them?*

*R: Yes we did. (Site 5, Doctor 1)*

Another possible outcome for patients subject to welfare of the child concerns is *their* withdrawal from seeking treatment. From the descriptions given by clinic staff, while very few prospective patient were refused treatment by the clinic, it became clear that a larger number of patients 'disappeared' or failed to pursue their search for treatment once potential problems or reasons for further investigation were raised by clinic staff:

*We don't normally see them again. You know, we see them at history and we do the history...and they just never come back basically because the doctors have said to them, 'While you're actively taking drugs or whatever we're not going to give you any further treatment'. (Site 18, Nurse)*

*Of course that's incredibly difficult to quantify because they just may never turn up to clinic again and therefore we wouldn't have any evidence at all to try and quantify that figure. It would only be the ones that have seen [the Counsellor], it comes back to me, you sit down and go through it again and fortunately, remarkably few people that that's happened to. But is there an attrition rate along the way? Probably but difficult to quantify. (Site 17, PR)*

It is obviously impossible to know what happened to these patients, but there was some speculation that they might seek treatment at other clinics:

*There's quite a few cases where the patient will...well when I say quite a few, of the very few we have, most of them will actually decide, you know, not to bother. And what's interesting there is that they could just...they could very easily learn from the process here and then go elsewhere but it's not our job to police these things so we would hope that there were robust systems in place in other centres. (Site 18, PR)*

## 5.42 Exclusions prior to the clinic

All clinics *had* thus refused treatment to patients on the grounds of welfare of the child concerns; such decisions were, however, very rare. Given the relative uniformity of responses across the set of interviews, we can be confident that it is very unusual for the final outcome to be that there is no possibility that treatment will begin. As the fieldwork went on, however, it became clear that a larger number of prospective patients are excluded from treatment by PCT funding criteria, a point raised by previous studies. When staff were asked if patients might be excluded prior to being referred to the clinic on welfare of the child grounds, most said no. However, when asked about the criteria exercised by PCTs in rationing funded treatment provision, it was clear from the responses that some patients must be being excluded on grounds that have some crossover with welfare of the child concerns, sometimes precluding the presentation at clinic of welfare issues.

### Age of the prospective parent

Only one (private) clinic had no policy on patient age, judging each new patient on an individual basis. Elsewhere, staff talked of upper (and sometimes lower) age limits for female patients imposed by PCTs, usually at between 38 to 40 years of age.

*There...there isn't a male one. Female age is different per PCT, for instance for Wales a patient must have been referred by I think it's 38 and 6 months whereas locally, most of the other ones are 40 so the referral must be received by...before the fortieth birthday. (Site 14, Nurse)*

Most clinics had their own upper limits, usually higher than the NHS ones, and often differentiating between women able to use their own eggs and those recommended to use donated eggs. The upper age limit for using their own eggs ranged from 43 to 45; using donor eggs, the upper limit ranged from 45 to 55, with most settling at 50. This finding applied to both NHS and private clinics.

Looking back over the transcripts, it is sometimes difficult to determine when staff are talking about funding criteria and when they are talking about clinic criteria. Age restrictions were justified on the basis of the likelihood of successful treatment, rather on the grounds of 'welfare concerns' about creating older parents. At three clinics, staff mentioned upper age limits for male patients, one at 52 the other two at 55. Most clinics did not have an upper limit for male patients; however, concerns were cited about couples with a large age gap where the male was considered elderly. The issue here was primarily one of whether the prospective mother would have a supportive social network were her partner to die during child's first 18 years.

### BMI

All of the PCTs had upper limits for maternal BMI, usually at around 30. Clinics also had their own, usually higher, BMI limits that would apply to self-funding patients. Again this was not justified in welfare of the child terms, but framed as a significant factor determining the efficacy of treatment, and also containing some issues of patient safety (for example during anaesthetic) and the practicalities of treatment (for example sufficiently large and strong equipment).

### Smoking

Most PCTs were reported as requiring funded patients to either be non-smokers already or to undertake a smoking cessation programme:

*R: If they are smokers, we have to throw them back to the GPs for a smoker's cessation programme and we need to get a letter back to say they have successfully completed this and they have given up smoking.*

*I: What does this make people do, because with the smoking thing I mean presumably people...*

*R: They learn to lie. (Site 1, PR)*

*Smoking status; although the majority of them [PCTS] obviously prefer people to be non-smoking, the Welsh ones actually say that they must be on a smoking cessation programme should they be smokers to proceed. (Site 14, Nurse)*

*R: They're not allowed to come through if they're smoking either, on the NHS.*

*I: And that's for all your PCTs?*

*R: Yes.*

*I: Do people just say they don't smoke, or do you...?*

*R: They say they don't smoke and we do quite often...we have had situations in the past where we have smelt smoke on people because we have no perfume products in the unit as well, so we get quite sensitive to smells, so a couple of times we've had situations where people have come in for their scans or whatever and they reek of smoke and so we do say to them, 'You're not smoking, are you?' and they say, 'Oh well no, but somebody else in the household smokes'. And we say to them, 'Well you've got to tell them that...' If we suspect... we've changed it so that now when they come through for a licensed treatment, there's another form that they sign which is no-smoking agreement...and they actually get told that if we think they're smoking, we can do a smokaliser test on them...And we can stop treatment if we think that's the case.*

*I: And that's all to do with funding?*

*R: Yes...And also the effect to the child – unborn child and smoking.*

*I: Right. The foetus?*

*R: Yeah. I mean we're not dealing with foetus as such but, you know, they've got to stop at this stage, really.*

*I: But it is a welfare of the child issue, rather than a sense of the effectiveness of treatment, do you think?*

*R: I think it's a mixture. Yeah.*

*I: And can you see that happening, people being refused treatment because of smoking?*

*R: They have been. Yes.*

*I: Right. And so not just refused funding, but refused treatment?*

*R: Well we call them up off the waiting list. Once they're told that they can have treatment we then organise information sessions and get them into their first cycles so anybody who has said on their history that they are smoking or anybody that we think is smoking, we just don't call them up...And we say to them, 'We can't you call you up until you've stopped'. (Site 18, Nurse)*

There were variations in the degree to which clinic staff were happy to police non-smoking requirements on behalf of the PCTs or were happy to 'turn a blind eye' to patients they suspected of smoking. There was also a noted discrepancy between the number of patients 'admitting' to being smokers when presenting for private treatment and the number prepared to admit this when applying for NHS-funded treatment. A number of interviewees spoke of patients 'learning to lie'.

#### Previous children

Most PCTs, it was reported, place restrictions on couples receiving funded treatment if they are already parents. The stringency of these requirements varied considerably. Some PCTs, respondents explained, will not fund treatment when either partner has living children; others will not fund treatment if there are any children under 18 living with the couple; and at least one was said to even refuse to fund treatment if the couple have had a previous baby that has died:

*It depends, [name of PCT] will not pay for any cycles if either of the couple had previous children, whether they've...interestingly enough, whether they've survived or not...So you have somebody who had a cot death or a...anything like that and they can't have treatment or if they gave a baby away for adoption they can't have treatment. But Wales, will allow a cycle of treatment, or two cycles of treatment if...so long as the children don't live in the household. (Site 18, Nurse)*

*If they already have children or either partner have children, then they are not eligible for NHS funding, because NHS funding in most PCTs that we deal with say that a child in either partner means that they are not eligible for treatment, so sometimes they write and they have*

*got children and they tell me that it's all a bit of a mistake, they haven't really got any children.*  
(Site 1, PR)

In common with a few other respondents, the above Person Responsible thought that such requirements meant that patients might try to lie about having had previous children in order not to jeopardise their chance of funding.

#### Relationship stability/longevity of the relationship

According to respondents across the sample, most PCTs required prospective funded patients to have been in a relationship for about two years. The definition of 'a relationship' was usually thought to be evident in cohabitation. Some clinics also had their own criteria, usually for a slightly shorter period of cohabitation. This, of course, was only applicable to couples, as single women could be treated at all but one clinic, but there were variations from one PCT to another in whether single women could receive funded treatment. Such rules were sometimes described as being difficult for clinics to work within as they were required to determine whether patients presenting as a couple, were in fact a 'couple in stable relationship' according to clinic and PCT guidelines. The second difficulty arose for patients whose relationships had not reached the two-year period, or which broke up while the patient was on the waiting list for treatment.

For women in their late 30s, who might be in a new relationship or who might change partner while waiting for treatment, this type of scenario was reported with varying degrees of sympathy for the women concerned, but overall women in such a predicament tended not to be talked about in very sympathetic terms. Coming to the clinic with more than one partner over a number of months or years was generally frowned upon, and treatment could not proceed as agreement to treat was granted to a couple, not an individual. Women who did not declare that their partner had changed but merely returned to the clinic with a new man were seen as especially problematic. Establishing relationship stability could lead to patients attempting to deceive clinics about their domestic circumstance and to clinics treating as suspect, patients who had been less than upfront about their arrangements. In this regard it was sometimes difficult to be clear whether the restriction was imposed by PCT criteria or whether clinics and staff had their own views about people not in stable relationships:

*R: I think it's live together for a year. Yeah. And be living together unless they've got a very, very good, good reason behind it. So as soon...I think it's the smell a rat sort of law of thumb; as soon as you think hold on a minute; what they're telling us doesn't match with what this...what the documentation...*

*I: Yes. Is that a kind of...is that a welfare of the child thing because you're thinking, 'Oh, what will the future of this childhood be?' or is it that you think... is it because you need honesty?*

*R: I think it's actually honesty. I think it's more...What you said, it's more trust because there's a trust relationship and, you know, they expect to trust us to do things right and we kind of expect them to tell the truth because, you know, there's...obviously one doesn't want to speculate on any...on any couple and certainly not any individual couple but if you can't trust the couple or the patient individually, you know, it's not very grounds for a relationship where you're saying, 'Take these drugs on this day. Make sure you tell us about this', where we're all trying to get the best result but how can you trust somebody who's basically lying to you?*  
(Site 8, PR)

## 5.5 Views of changes: problems and solutions

As we discussed earlier, *Tomorrow's Children* (HFEA, 2005) concluded that there should be 'a general presumption in favour of providing treatment for patients who seek it', but given the welfare of the child provision in law, it set out that clinics must continue to take 'account of the welfare of any child who may be born as a result of treatment', and that this should be done through a process of risk assessment. The consultation that followed *Tomorrow's Children* resulted in new guidance, summarised on the HFEA website as follows:<sup>19</sup>

- That clinics should assume they will provide treatment unless there is evidence that the child is likely to be at risk of serious harm;
- That there should be a clear focus on areas of serious harm, with vague and subjective social questions removed from the assessment; and
- That clinicians should use their professional judgement to decide which cases warrant further investigation rather than being obliged to contact a patient's GP in each and every case.

The subsequent revised Code of Practice states:

G.3.2.2 The centre should carry out a risk assessment in relation to each patient and their partner (if applicable) before any treatment is provided. The assessment should be carried out in a non-discriminatory way. In particular, patients should not be unfairly discriminated against on grounds of gender, race, disability, sexual orientation, religious belief or age.

G.3.3.2 In order to take into account the welfare of the child, the centre should consider factors which are likely to cause serious physical, psychological or medical harm, either to the child to be born or to any existing child of the family (HFEA, 2007)

As we argued previously, this approach can be read as seeking to liberalise the regulations, as well as seeking to generate a simpler and less burdensome assessment process (ie a simple risk assessment, envisaged as taking minimal time and effort for the vast majority of prospective patients).

Following this change to the regulations, the law was amended. The existing wording of section 13.5 of the HFE Act was amended and the phrase 'the need of that child for a father' replaced with 'the need of that child for supportive parenting'. According to subsequent guidance issued in the HFEA's Code of Practice (HFEA, 2009, 8.11), 'supportive parenting', was defined as follows:

*Supportive parenting is a commitment to the health, well being and development of the child. **It is presumed that all prospective parents will be supportive parents**, in the absence of any reasonable cause for concern that any child who may be born, or any other child, may be at risk of significant harm or neglect. Where centres have concern as to whether this commitment exists, they may wish to take account of wider family and social networks within which the child will be raised. (Our emphasis)*

Overall, it can be argued that a central aim of these commentaries about the welfare of the child assessment was to give a sense of certainty about both the scope and purpose of assessments. The guidance can be read as underpinned by a view that staff can and should work on the basis that they can be sure patients do not present a risk to children born in the future (to the contrary, they will be 'supportive parents') and can be treated.

Now, we consider the impact of this revised law and guidance, as described by the professionals interviewed, on clinical practice and their interpretation of its meaning; this section discusses the views expressed by respondents about the welfare of the child requirement as a whole. We discuss their responses to questions about the changes to the HFEA guidance on the interpretation of the welfare of the child assessment following the *Tomorrow's Children* consultation, and the change in wording of Section 13.5 in 2008.

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<sup>19</sup> <http://www.hfea.gov.uk/510.html>

### 5.51 Perceptions of the welfare of the child process: conceptualisations of risk and what is knowable

Most interviewees considered the new welfare of the child assessment to be a risk assessment, and the attempt to gather the information about indicators of risk required by the Code of Practice was taken seriously. There was some ambiguity in their accounts of 'risk', however, between a strongly expressed view that patients are in general honest and may sometimes have good reasons for not being so, and, on the other hand, a consciousness of uncertainty about what can be known. Hence while most interviewees on the one hand felt that patients were generally open and honest, and that most patients were absolutely 'normal', with no welfare of the child issues, this view co-existed with the view that anyone with something serious to hide could and would do so.

#### Patient honesty

A high premium was placed on patient honesty, and some reported that patients found to have tried to deceive the clinic, for example about their partner's identity or the existence of previous children, had been refused treatment even before a welfare assessment had begun. In such cases, it was difficult to tease apart if this was because dishonesty was felt to indicate a welfare of the child concern, or because proceeding to treatment required a relationship of trust between clinic and patient, undermined by patient dishonesty. Staff spoke of the need to trust that patients would follow instructions concerning their medication, and how patient dishonesty in response to non-medical questions would lead clinics to have reservations about whether that particular patient-clinic relationship would be manageable.

There was acknowledgement that access criteria, in particular those relating to funding, could force patients to lie or at least 'say the right thing' in order to access funding. Smoking in particular and the existence of already-born children were the most commonly-cited examples of patients lying. Staff sometimes took the view that this was a serious breach of trust but others were inclined to a more sympathetic view that patients were forced to jump through certain hoops and some were better than others at realising how to play the game.

Views varied between clinics and between professionals about how well they knew their patients by the time treatment began. Some felt that the initial doctor consultation, sometimes lasting over an hour, where medical and social history was taken, provided an opportunity for an in-depth discussion about very personal issues, allowed doctors to get to know their patients and perform an informal welfare assessment. This kind of perspective tended to contain the view that considering the future welfare of the child was intrinsic to a holistic professional assessment of the patient, something that was more meaningful than the act of filling out a self-declaration form. Doctors in particular tended to express a relatively high degree of confidence in their ability, derived from their professional experience, of exploring difficult issues and asking the right questions and of making professional judgements.

*You feel confident because if you have the experience and you've been doing that for twenty years and you have seen couples in different arrangements and everything, you feel confident and competent to do that. And also you will always be supported by the knowledge that...there is a structure within the unit that you work in to help with these issues. Whether it is a counsellor, whether it is a team, whether it's yourself, so the whole process is...Whenever we are coming across unusual scenarios, it's shared so you accumulate. It's not just the cases that you see, but the cases of other people. (Site 7, Doctor 1)*

A number of respondents remarked that they were often surprised at how open and honest patients were, and this was usually taken as an indicator that patients did not have anything to hide:

*I always find it quite surprising how honest people are about those questions. (Site 11, Doctor 3)*

*I think mostly patients are honest. (Site 4, Doctor)*

*I think they want to be honest, yes. (Site 2, Doctor)*



*I think that if they really want this treatment then I think that they probably do open up with the doctor. (Site 11, Nurse)*

Some said that patients could be remarkably honest in raising issues that were likely to be considered welfare of the child concerns.

*I've been surprised at the honesty that patients will come back with, even when they know that you might decide that it's inappropriate to treat them. (Site 5, Doctor 2)*

*We have some patients that are very open and upfront about it and come along saying, you know, 'I need to tell you this', and sort of get it out in the open straightaway. (Site 6, Embryologist)*

This honesty tended to be seen as helping the patient's case for treatment as it suggested that past problem behaviour had been dealt with, and patients would cooperate during further investigations. This is illustrated in the cases described elsewhere, where we detail how patients with convictions for harming children were given serious consideration if they were open from the beginning about their past and entered into a constructive relationship with the clinic to find evidence that they should be no longer considered a risk to children.

However, others felt that patients were not always open about everything, in this case, because they were wary of medical professionals:

*People worry about it because they see doctors as being part of the establishment...and when you explain to them, you know, your low sperm count might be because you drink too much but I see that you're only drinking a glass of wine a day... then they just say, oh yeah I've been smoking or whatever. (Site 1, Doctor)*

Or here, that the NHS funding criteria exacerbated patient dishonesty:

*I: I think people tell you what they think you need to know. And we've seen that with smoking. You know, what's happened with smoking now is the NHS have said, 'We will not fund IVF for smokers,' so nobody smokes anymore...and, you know, they come through the door stinking of fags and, 'Oh, I gave up two years ago doc'...and little things about funding as well so if you've unexplained fertility you have to be trying for three years so every couple that comes through the door; 'How long you been trying for?' 'Over three years, doctor'. You know, so I think couples are very aware that there's being some type of assessment being made and suitability for treatment.*

*R: ...so is the funding the thing that alerts them to those kind of criteria, do you think?*

*I: I think it is primarily. I have to say in the private clinic we get people saying, 'Yeah. I'm on 10 fags a day', or three bottles of whisky a day. So yeah, I think people in the private clinic don't feel they're being judged so I think the funding does drive a certain level of response...It's human nature. (Site 17, PR)*

The same respondent also felt that patients struggling against age criteria could also be motivated to present a known sperm donor as a partner, because treatment could proceed more rapidly:

*...we've had a few deceptions before. Most of them have been where women have turned up with different blokes...And essentially, you know, it's a bloke who's being a donor...That happens frequently. And we've become less...we have become less anxious about that than we used to be, although what's really interesting is...is in a couple of months' time we have a new software system that works with patient photographs so actually patients are going to have their photos taken like the airport – a little camera when you're coming through clinic to check who you are. There is a logistical issues, though, in that if the guy goes down a known-donor route, he's treated as a donor which means his sperm has to be quarantined for six months and if that woman's just turned 42 she may feel I haven't got six months to wait and therefore she'll say, 'Oh no, he's my partner, when he can be X, Y, Z', but of course what's put the kybosh on that a little bit is now these new 'consenting to be a parent' consent forms that we have, where actually the guy is saying, 'Yes. I am going to be the parent of this child', and we've had conversations with people in the past about these cases of child support*

*where you can't sign away, so you can't get a letter from the woman saying, 'I'm just being a donor, doing her a favour because I'm a mate', because actually she can sue for child support and the law will be on her side. So we've had those conversations once or twice around child support issues and...and we've had a few interesting cases here being...where we've been involved in the litigation for the child support, so we've had...and one of them was under welfare of the child. (Site 17, PR)*

Most professionals expressed a degree of doubt about whether the self-declaratory character of the WOC form was a reliable way of gathering information, and some felt this left professionals unable to fulfill their obligation with regard to protecting a child from future harm.

*...we're left expecting them to be honest with us, which, you know, not everybody will be. (Site 11, Doctor 3)*

*Because the onus, I feel, is very much back onto the patients. That they have to declare anything and who's to say they're going to be honest with us. (Site 18, Nurse)*

*I think people can tell you whatever they want and I know you could turn round and say, 'Well...' you know, if they've signed that form then that's...they're responsible adults and it's up to them, but you also feel obliged...you feel as if you have a responsibility to that child if you've treated them, if that child is... is then put at risk or at harm. (Site 16, Nurse Manager)*

There was a widespread view that any patient with serious indicators of WOC concerns, such as convictions for harming children or social services involvement with existing children, would be unlikely to tick 'yes' to questions on the HFEA form, and that therefore 'you never know':

*I think it would be very easy for people to move into a different area and just lie. But you have to have some kind of confidence in people's integrity, don't you? They do have to provide proof of identity when they actually come through for treatment...But again, you know, people...if they know the system they can buck the system, can't they? Very easily. I mean, they can say, 'Yes, we've been living together for years', and, you know, 'There've never been any problems and we've never had any children before'...I mean sometimes with the ladies you can obviously tell that, but at this stage when we're just doing investigations, we can't, you know, say, 'Can we just have a quick look at your cervix and check if you've got any caesarean scars', and things like that! (Site 18, Nurse)*

*R: Often they would tick a 'yes' for a medical condition that's really not that important, for example, they might suffer from asthma or arthritis of some kind so those things I tend to just ignore because that's not really what the welfare of the child is about, but if there's been an issue with... drug abuse or abuse of... children then obviously that...will be taken out but, you know, these patients were not really... it's silly to actually think they would volunteer anything like that...we would be at their mercy, so to speak. If they don't volunteer that information then we will not know about it unless somebody else tells us about it, so it is possible that through this assessment something like that could be kept hidden from us.*

*I: From your experience, do patients tick 'yes' if there's an issue?*

*R: No. I've never seen somebody tick 'yes' for something like that.*

*I: OK. So how useful is the form in that respect then?*

*R: Maybe not that useful. Drug abuse has...I've seen that being mentioned before, they were willing to admit to that and then if they have been on a rehabilitation programme we would write to the GP and ask if that had been the case...So that's something that maybe...slightly less of a stigma. But child abuse, anything like that, never had anybody mention anything like that. But it serves to illustrate the principle that if the patient doesn't volunteer then we will not know it, so I would say in that sense the form is more a question of the HFEA showing that they are doing what they can to try and identify a problem and if the patient withholds information and the patient is guilty of misleading, responsibility in a sense is staying on the patient and taken away from HFEA. (Site 2, Doctor)*

## 5.52 Views on the forms

Another way a sense of uncertainty was expressed was through criticism of the slimmed down risk-assessment process. Although it (or a version of it) was widely used, support for a less time-consuming approach was expressed alongside reservations; attitudes were ambiguous. Indeed, a relatively small number of interviewees thought the HFEA welfare of the child patient history form was simply useful or appropriate. Negative views of the form were based on a variety of reasons, and not all of these related to issues about how to assess risk. Some, however, thought it too sparse:

*If I'm honest, I don't feel they're as detailed as they could be. I feel that there are areas that probably could be covered as well. (Site 18, Nurse Manager)*

*I mean I...I feel this is a very weak tool, truthfully. I think that we had been...it's been watered down enormously and it's now something which given it now happens once patients are within the system and at a decision point, it's true, but still within the system it's much more difficult to say no to people. (Site 11, Doctor 3)*

Others held the view that it got lost within the mass of pre-treatment form-filling:

*The relevancy of it is just another form to fill out. That's how important it is. It's not that important in the great scheme of things. (Site 8, Nurse)*

Doubts about the usefulness of the form often seemed to reflect deeper misgivings about the possibility of meaningfully assessing risk in the way that is demanded:

*I mean I just don't see how any form and any one person, you know, meeting a couple trying to get pregnant can honestly really say they know that there's no welfare of the child issue. (Site 3, Nurse)*

*Well, you know I don't think that we can ever be – ever be confident really, I mean there will be cases where things happen that we are not aware of. (Site 1, PR)*

*I: And so do you think that the guidance allows you to feel fairly confident about what you're doing?*

*R: No...I'm sure we miss cases...Do I feel confident that we are thoroughly and fully assessing welfare of the child issues? The answer is no I don't. I'm not sure if there is a really good way that one can do that that is fair to people. So I think you just have to do the best you can. (Site 17, PR)*

*I don't think we'd ever feel 100 per cent confident. (Site 6, Embryologist)*

*R: ...sort of guidance from your...your peers, as it were, but very often you're not seeing both parties so how can you do an assessment if only one party turns up for consultation and you might only see that...say the wife'll be the one who comes, you might only meet the husband once and never see him again. And how can you judge on once and you could say how can you judge on twice? How many times you need to...you haven't got access to the home environment...The devil doesn't come wearing a big thing across his head saying...*

*I: And do you think that...would you like to be able to assess in a more thorough way, or do you think it's just impossible to do that?*

*R: I think it's impossible to do it. (Site 3, Nurse)*

*R: Well because we need to decide what to do...what we're trying to achieve for the welfare of the child process and...and what we're trying to achieve is will these children be raised in a happy environment and that form has absolutely no chance of being able to achieve that. How can you possibly, possibly judge? Even if we had a team of social workers come round and interview them going through the home, I couldn't possibly judge what the situation would be in eight years' time.*

*I: OK. So it's not that...you think the form is incapable, you think actually there is no way of knowing it.*

*R: Exactly or at least in any kind of reliable way.*

*We take the attitude that we're required by law to make an assessment. The HFEA have given us a form where we're to make this assessment so we tick that box that way...I mean it's got the specific questions in it so you get that detail but it doesn't tell you about the character of the patients and who they are...I keep away from trying to be judgemental. I think we're trying very hard not to be judgemental but I think they're very specific questions there that are useful to have for what they are but they're not going to tell you everything about welfare of the child. They tell you some very specific things that highlight the need to discuss it further but we pick up other things...if somebody's got a treated psychiatric problem and they think they're stable, it's not going to tell you an awful lot from there, for instance, that they're not. You need to then to pursue that further so I think we probably get as information without the form, just from the other things, apart from those very specific things about criminal records and that kind of thing. (Site 15, Doctor)*

This moves towards a view expressed by others, that assessing patients is simply an intrinsic part of clinical practice, developing from history-taking during consultations, not form-filling.

*I think that that sense of responsibility would be there anyway. I mean I...you know, I think it's making assessment about, you know, whether they're...you know, the couple sat in front of you are suitable to be parents and I think, you know...I think yeah, it would...it would be innate anyway, rather than having a form. (Site 13, Embryologist)*

This doctor was concerned that while the WOC process was ineffectual at ensuring the welfare of the child, and the requirement to perform a welfare of the child assessment was inherently discriminatory against the infertile, but also seems to accept that clinicians have a role in working through potential issues while avoiding making judgements of them:

*I'd say it's the same value as it was 20 years ago; a complete waste of time...Always has been. Because it doesn't...it's discriminatory against fertility couples for a start because no one else in the general population fills them in...whatever a patient fills in, they're highly unlikely to admit to something and it therefore...if we fill it in, or if they...they lie on there, they're still going to get treatment, and people change, so what might be the case when they see you to begin with could change...And it's not policed, so if someone does say anything positive, no one looks into it and it's extremely hard to police anyway, because of confidentiality issues...it's discriminating against infertile couples. When an infertile couple are so much more motivated to be good parents from someone who just happens to conceive naturally with even unwanted pregnancies...If you're going to do that, you also need to assess the whole population...It shouldn't be done at all...the trouble is you immediately discriminate, but to give me a form to fill in to assess somebody's suitability to be parents, I would like to think that if there was a problem, we would pick that up at consultation...And a piece of paper isn't the answer. It's a consultation with a couple to work out if there's a problem...I think about the welfare of the child just in consultation. And I skip over the welfare form. I see that they've ticked everything. We tick our bit and sign it to say that we've gone through the motions but I'm not thinking in a consultation about what...what will they be like and then equally, who am I to judge? If I think oh my god, that's going to be a terrible parent or people have got totally unrealistic expectations, you could...you can't then discriminate and say, 'Well we're not doing it then'...the few cases where we've not treated, we picked those up at consultation – not through a welfare form. (Site 16, PR)*

### **5.53 A presumption to provide treatment**

Many respondents thought that the revised HFEA guidance did not have significant implications for practice, because there had always been a presumption to provide treatment:

*I think it was already the way we were seeing things, yeah. (Site 10, Counsellor)*

*I think that's what...I think people were basically already doing it, yeah. (Site 3, Counsellor)*

*I think we were doing it anyway, it's just we didn't have to do it in the same way anymore. (Site 15, Doctor)*

*I think perhaps it has been made more prominent after the recent changes but, you know, one...has always to work on the principle that people are innocent until proven otherwise. (Site 7, Doctor 1)*

However, this Doctor thought the new guidance had made possible a more positive approach towards new patients.

*I: And do you think it solved problems that were previously there?*

*R: Oh yeah. No doubt about that. I'm not sure it solved any welfare of the child problems, but it solved logistical paperwork, not being able to proceed with treatment until the GP had sent the letter back so yes, it made management of the couple's treatment easier. No doubt about it. I also felt much more comfortable philosophically with, you go into this wanting to treat someone, as your default position. I think that's a far healthier situation to be in than to take on some type of state assessor of suitability to be parents.*

*I: And you think that's definitely what was there before?*

*R: That's how we felt, I think. (Site 17, PR)*

Others had reservations about the new explicit presumption to treat and its impact across the sector, if not at their own clinic:

*R: I think there's more of a shift of a presumption to provide treatment. I don't think it's a particularly good idea because we've heard of cases in other clinics where people have been treated and you wouldn't possibly have treated them and if we've turned people down here, we know that they've gone on elsewhere and accessed treatment.*

*I: So do you think this makes it harder for people to refuse treatment?*

*R: I think because assisted conception is a business, it does make it harder because, you know, you're turning business away and especially if you know the clinic down the road will treat them whatever, but I think as a clinic, you have to have integrity and you have to have standards and...that's very clear in this clinic, that we're very clear that, you know, we wouldn't compromise. (Site 12, PR)*

A couple of respondents talked of patients increasingly demonstrating a 'sense of entitlement' not just to treatment but to particular types of treatment, for example a same-sex female couple requesting simultaneous pregnancies, that may not be medically necessary to overcome infertility problems. This counsellor seemed to interpret 'the presumption to treat' as something taken on board by patients, which could conflict with welfare of the child procedures:

*I think there's always been a presumption to provide treatment in all honesty. I don't think that's necessarily changed in terms of the patients. I think that most patients who are referred don't think that there'll be a reason as to why they shouldn't go through for treatment and certainly in the incidences that I can think of where patients weren't, specially the case I was involved with, they couldn't understand why they couldn't have treatment. (Site 7, Counsellor)*

This doctor, in particular, felt that the balance has tipped too far in the patient's favour, making it difficult to justify the further investigation of patients about whom staff had 'hunches' of something being 'not quite right'.

*I think it turns the whole thing around from the way it used to be, to making the assumption that you will treat everybody unless you've a really good reason not to, and it puts the responsibility on us to set what we think would be the reasons for that which isn't bad in itself but it's simply that, you know, the way that it's now being phrased is that it's very much, there's really no reason not to treat anybody and the tone seems to be very much, you know, that the firmness which would have been there before has gone and the support you might get from the HFEA in terms of a challenge is going to be probably non-existent and I think it's those kind of things that you realise, you know, their view is you should treat everybody. You know, that's not quite what they would say because they would say, 'No. No. No. It's...' you know, 'serious harm'. But it's about trying to define what you mean by serious harm and that...that's...serious harm is a very major thing to try to define, whereas, you know, a discomfort or an uncertainty you might have, or unhappiness you might have – well that's not*

enough. And it's not enough to go and investigate and stop people from being treated. (Site 11, Doctor 3)

### 5.54 'Serious harm'

The new guidance promotes an approach that limits consideration of welfare concern to risks of 'serious harm'. We detailed previously the ambiguities that appear to pervade perceptions of assessing this risk, emphasising in particular a sense of uncertainty about 'knowing' if risky individuals had been identified, expressed by many respondents. Later in the interviews, respondents were asked to comment on whether they considered 'serious harm' to be a meaningful term for them, to explore further their perceptions of recent changes to the guidance.

Their accounts of what they considered to lie at the heart of this concept were varied. This clinician felt that the apparent 'lighter-touch' of the guidance coincided with a more liberal culture amongst clinic staff:

*Well I don't know if there's a difference between harm or serious harm, so putting the adjective in it is really immaterial. I guess it's important to state from the point of view that they all have to be taken into consideration but it's my impression that over the decade – over the last decade – the staff who...all of these things depend on the staff's commitment to their following it through and I would say that over the decade, the staff are more...have become significantly more liberal. (Site 4, Doctor 2)*

In this account, the move to risk assessment of serious harm is construed, similarly, as 'liberal', and taken to mean a shift in attention away from same sex couples, to instead a more universal concern with whether anyone seeking treatment will be a, 'good parent, whatever that means':

*I guess what I mean is someone that's going to be able to look after a child and the child is not going to be in danger physically or any other way and then we use the word 'good parent' I suppose, they'd be good parents, whatever that means... 'would this child be in danger; would this child be at risk?' That's all we are interested in really. It's not whether it's right that two gay men have a child or two gay women have a child; it's will this child be harmed, so what if the Dad's going to die before this child is 5? Will this child come to any harm mentally or physically? It's not ideal, but the woman's really together; she's got lots of money and she's got extended family all around her to support her, so when we go round and round in circles, that's the thing we come back to; will this child be damaged? (Site 1, PR)*

Some indicated they were less comfortable with the direction of things, and suggested felt that it was now very difficult to act in cases where staff felt that something was not quite right about a patient, as this could sometimes not really be defined as 'serious harm'.

*That's very strong, isn't it, and I think if there was anything where you thought crikey, this patient could be harmed you'd be really wanting to get involved. We had a patient who was a virgin...who wrote to us to have treatment and she'd identified the man that she wanted to be the father. She hadn't actually spoken to that man's wife...we never even got as far as treating this woman but that was clearly, you know...What sort of impression are you giving to give to a 14 / 15 year old who's discovering their sexuality in 15 years time if you are a virgin, you know? I appreciate that might not be serious harm in terms of physical abuse but it's not...a healthy attitude to sexuality. (Site 10, Nurse)*

At the same clinic, the counsellor cited another example where 'peculiar' personal circumstances were not easily construed as a welfare concern, but nevertheless made staff uneasy about offering treatment.

*R: Well we had a woman who was in her late twenties who came along asking for donor insemination and it transpired that she had never lived away from home, that she was a virgin, she'd never had a boyfriend and she effectively had no friends only her family um...and we just felt that that wasn't a healthy environment for a child to be brought up in and that it would be confusing for any child as to who was actually her mother or his or her mother given that there would obviously be a mother and a grandmother who were under the same roof,*

*and having briefly met the mother...I don't mean interviewed the mother but having briefly met her in the waiting room, I think she would have been the more important person in the child's life.*

*I: And how did you know how that decision was reached? I mean who was involved beyond yourself and the team, anybody outside of that?*

*R: I don't think so, no it was just me and the team. (Site 10, Counsellor)*

This Person Responsible thought that the change to a consideration of a risk of 'serious harm' was not only difficult to prove in advance of a baby being born, but also represented a diminished concern for the welfare of the child:

*I: ...and what about the other aspect of this change in the wording; 'evidence that the child is likely to experience serious harm'...what do you think about that wording?*

*R: Yeah. Unless there is evidence – what does that mean? What evidence do you need because you don't know until it's happened, do you, really? I think you have to go on...on what...what's happened previously, so going back to the...cases where people have children taken into care, I think that's an indication that there...the risk is much higher.*

*I: But do you think a case like that nowadays, there wouldn't be an automatic refusal but there might be a process by which...?*

*R: There would be...yeah. There would be a process and there would be a discussion but then I think staff would feel quite uncomfortable...if somebody comes back with this [the HFEA form] and has just put 'No. No. No. No.' and they've referred themselves to a clinic 100 miles away, nobody's going to know, are they, if there's any issues?*

*I: But do you think there were problems of inequity in the past that might have been overcome by this?*

*R: I think so. I think there's probably inequity full stop. I think some clinics will treat anybody and everybody and other clinics won't...But I don't know how you police that and how you say what the standard should be if...if there should be a standard.*

*I: ...and do you think the way that the guidance has changed allows clinic staff to feel relatively confident in what they're doing?*

*R: Well I think the focus has gone from welfare of the child. At one point, welfare of the child was paramount; absolutely paramount and I'm not sure that in some areas it is anymore or maybe in some clinics it is. (Site 12, PR)*

This slightly contradictory answer to the question, 'is there now a basis for common standards across clinics?' indicates the ambivalent view that while the new assessment requirements, and in particular the presumption to treat, bring to an end discrimination against social groups, the new guidelines are so minimal that they do not recreate a basis for common standards:

*There's no guidance about how you set about assessing the welfare of the child and I think the forms are very specific, very pointed for particular things and I don't think actually the... it allows for commonality at all. I suspect there is a reasonable degree of that because of this idea of presumption to treat. I can't imagine there are many units who are being very dogmatic or had a higher...much higher threshold for turning people away but maybe they did, you know...Maybe they were looking at people saying, 'Well you don't look like the right one, we'll send you away', you know. Maybe they were making judgements with decisions but I suspect that wasn't the case so I don't think it's probably changed things hugely. (Site 15, Doctor)*

The same doctor did not, however, think that it would be helpful to have further formal specifications for what should be considered to constitute harm.

*I think what we do is fine but there are limitations to what we can get from what...of what we would like to do but that's not going to be helped by writing more instructions. That's more to do with what's available for support really, which is a different issue to...to cover, I guess. (Site 15, Doctor)*

## 5.55 From GP-led to clinic-led assessment

A majority of respondents thought that the move away from mandatory GP approval was positive. There was a widespread view that the old system, which required sending a letter to the GP of every patient asking whether they had any welfare of the child concerns, and chasing a response, was not a useful approach. One of the problems identified by the respondents with the previous system of GP assessment was that significant delays could be imposed on patients and additional work created for clinics in chasing assessment reports from GP, for no real purpose:

*It was a nuisance. It was a nuisance...because if you didn't get a reply back from the GP, we had to presume it was OK, or we had to chase them all the time and that was just silly because most of the time it wasn't an issue and we had to chase the GP for another letter to say, 'Well of course it's fine otherwise why would I...' you know...it's frustrating for GPs, it was frustrating for us and it was just a nuisance...I don't think [the new guidance] changed what we wanted to do, it just made it easier for us to do it. (Site 15, Doctor)*

*...that was helpful because it meant that we didn't have to write a fatuous sentence on the bottom of all our letters back to the GPs to say, 'Can you tell us if there is anything', an expectation that they would so that was then relief in some ways because it was... it was just frustrating. People found it...GPs didn't find it helpful. We didn't always get replies. Were we supposed to chase replies and say that it was all OK, you know? Most of the time it was fine but we didn't feel that we were picking up extra things because of this and that so yeah, I think that was probably good thing to have gotten rid of. (Site 15, Doctor)*

Difficulties could also arise where patients declined to give consent for clinics to contact their GP, as under the old guidance, the clinic was then obliged to gain consent for other possible sources of background information to be contacted:

*I suppose there'd be issues with patients because if they were...they may not want their GP to know they're coming for treatment, you know, if you hadn't referred them, if they'd almost self-referred so there were issues there. (Site 12, PR)*

There were also concerns that GPs' knowledge was limited and they may not be sufficiently motivated to provide a reliable assessment; in other words the previous system did not lead to *enough* scrutiny:

*I: Were there problems with the previous system?*

*R: Yeah, I guess so, because you didn't necessarily get a reply back from the GP. And also there may have been cases where the GP responded and said, 'Oh yeah, everything's OK', when, in fact, it may not have been. There were some couples that took the forms to the GP and asked them to do it and the GP charged them so yeah, there were issues but I think it felt maybe a little bit more of a security blanket for us. (Site 12, PR)*

*I think we often found with GPs that they wrote back to us and said 'we don't really know this patient and we've only just joined the practice' or 'I've only met them once' particularly with men who hardly ever go to the GP...on the other hand there were some occasions where GPs would flag things up. (Site 10, Counsellor)*

*...well to be honest with you, towards the end we were becoming pretty kind of accepting of the fact that the forms filled in by the GPs couldn't always be relied upon and they weren't you know, I think, when we first had the 2005 things, I thought: oh great, this will now simplify it because this is what happens de facto....also we didn't know just how reliable those forms were filled in, busy GPs ticking these things in and only ticking in what the woman there or man there has told them...I found that the GPs were not, you know it was good that it kind of provided us with a little bit of cover, it protected us a little bit, but I always had anxieties about just how thorough they were...It's not like you're living in the leafy shires where the GP's known you since you were a little girl or boy, you've been with that GP for six months so if the GP says you haven't got any drugs or you don't do this or that, it's only because they've asked you. They've put the form in front of you saying 'do you take drugs'? – no, OK. So you might as well just give the form to the patient to fill in. (Site 1, PR)*



Other respondents were pleased with the change as it has become a more meaningful assessment:

*Well I think it was a good move because it...basically stopped us sending loads and loads of questionnaires to GPs saying, 'Do you think they're going to make good parents?' Which, you know, which I think was a paper exercise and tick-box HFEA thing for their...that was their particular thing for inspection that year. I think it was a good thing...we changed our practice, so, you know, we moved away from this questionnaire. Was it in the notes? Are we being audited against the next inspection? To a more scenario of was there anything in the GP letter? Was there anything came up at the consultation? Let's do that. So it was more of an individualised assessment when we said...when we thought there was a bigger risk as opposed to the same blanket evaluation for everybody. So it did change our practice. (Site 17, PR)*

*I think you feel happier to a certain extent if you're making that assessment yourself. I mean I...you know, the GPs have got some information. You've got another one...if you've got a couple sat in front of you I think you've got a fairly good balance but you don't know their history but then if there's...if there is no history and you haven't see your GP for eight years, you know, that they...they've got nothing to say either, so I think it was probably for the best. I mean, you know, we still send those letters out, it's just that we can make that assessment ourselves with that. (Site 13, Embryologist)*

However, some were less positive about the changes to practice, seeing the removal of the need to contact the GP as part of a problematic process of 'watering down':

*I mean I...feel this is [the new system of risk assessment] a very weak tool, truthfully. I think that we had been...it's been watered down enormously and it's now something which given it now happens once patients are within the system and at a decision point, it's true, but still within the system it's much more difficult to say no to people. (Site 11, Doctor 3)*

Some felt that GPs in particular had been a reliable source of information on which to base assessments of patients. The requirement to get GP approval to treat a patient offered an additional layer of safeguarding.

*I think in terms of welfare of the child assessment, I think the changes in procedures of involving the GP more has been hugely significant in terms of picking up issues...I mean I feel quite torn about it because I suppose in a sense, again, I do feel that people, you know, for anyone that can conceive naturally, nobody needs to go through this. Whereas you know, because people can't conceive naturally they have to jump through hoops almost, it feels and that feels incredibly unfair. So in that respect, it's been a forward step for the patients but I think in terms of picking up the very few cases but the very real cases that there are, it's been a backward step. But again, if you, I suppose statistically, if you look at three cases over thirteen years, it's a very small incident base but nevertheless. (Site 7 Counsellor)*

*So we stopped badgering the GPs so much...Which a lot of us felt was not enough... We felt it wasn't a.. change for the better...But I think the GPs probably felt it was very much a change for the better because we were no longer having to get these forms back. (Site 18, Nurse)*

*I think we felt a little bit cut adrift, in a way, because we felt...when we were writing to the GP, we felt we had some backup and some support and it was a way of actually accessing information that we ordinarily may not have so when we didn't need to do that it was a little bit difficult to know what we should be doing. (Site 12, PR)*

These latter responses perhaps explain why, as discussed previously, some clinics are still routinely asking GPs for any relevant information about prospective patients (with the difference between the old and the new systems being that the absence of a GP response is interpreted to mean that the GP has no welfare of the child concerns issues about the couple). Such clinics tended to see greater continuity with the past.

*I'm not sure that it did [change much]. I mean I don't think we changed our practice at that point because we were already doing what we do now. (Site 10, Counsellor)*

## 5.56 'Supportive parenting'

Interviewees were asked for their views of the change in the wording of S13.5 of the HFE Act in 2008. In the previous section, we discussed the how staff viewed the removal of the requirement to consider 'the child's need for a father', but here we discuss respondents' views of the replacement wording: 'supportive parenting'.

Some felt that the change in the wording of the law impacted on practice in a 'liberalising' direction:

*... it did mean that we were able to treat same sex couples and single women easier.*  
(Site 18, Nurse)

*R: I think clinics have been more open to lesbians, you know, gay sort of different relationships. I think they've been more open to that, whereas before I think some...you certainly, you know, you used to have as a 'we can't treat them because of that' and I think now we can't...you can't get away with that. If that makes sense? You know, because you can't hide under that and say 'oh, no way'. You know, 'because of this we can't treat single women. We can't treat lesbian women. We can't treat, you know, gay men' or whatever.*

*I: So what would have happened with lesbian patients before 2008 then?*

*R: Here, there were a couple had come through but not very many. But...certainly that's why I think we're seeing more now. You know, I think there was a few but...it wasn't so open then and we didn't get even as many requests, let alone, you know, have the people coming...*  
(Site 9, Nurse)

Others reported that their own clinic was already treating single women and same-sex couples prior to 2008, so viewed the wording change as having little practical consequence. Indeed, some presented the 2008 reform more as a response to prior changes in practice, and as a reform that influenced subsequent changes:

*I think that our practice has changed over the years so I think these changes, in a way, were catching up with the way we were moving towards.* (Site 1, PR)

*I think this code of practice caught up with what was happening in clinics, so I think in that scenario, clinics led the way and there then became a change in the code of practice to really reflect what people were saying in the clinics and so it's been...and I think that's good. I think you should be able to... have a code of practice that's flexible because...and at the same time I think that bodes well for good law-making that allows you to legislate an act that you can...we can play with without having to go back to parliament to change a law so that's quite...I think that's quite a good reflection on the law that we have, that it's not too bad a law.*  
(Site 17, PR)

*I don't think it changed anything hugely for us because we were already in a situation where we were dealing quite regularly with...with single-sex couples, single women and we'd already established a process, if you like, and...and it was across the board so changing that, I don't think my discussion with single-sex couples has changed just because I don't have to take into account of the idea of the father because there's still the discussion to be had about the support for things that we've talked about, so I still address them in the same way so I don't think it changed our practice particularly. What it was designed to do was to avoid people turning people away because they were single-sex couples. That wasn't our issue. That wasn't really a problem.* (Site 15, Doctor)

These respondents thought that the law was catching up with broader social changes:

*I think it did happen in parallel and society has moved and there's more acceptance of single women having treatment and there is more acceptance of same-sex couples having treatment, so that change in the welfare of the child just came to mirror what is happening in society, so it was not to introduce change, but to mirror the change that has already happened.* (Site 7, Doctor 1)

*I don't think the 2008 law had that much of an impact because I think there've been a lot of single families around anyway and, you know, people split up and, you know, there's not always a father around. (Site 3, Counsellor)*

This doctor suggested that although their clinic was already recognised as being prepared to treat same sex couples and single women, the change in the law may have effected a broader cultural shift, making such patients more likely to request treatment, more confident that they would be greeted positively:

*Overall it appears that the proportion of single women and single-sex couples has increased over time. The absolute numbers haven't changed enormously but they've gone up a little bit over that time...with the legal changes...it has to be said, in the paper that was just submitted, that increase might in part relate to the idea that there's perhaps seen by those couples a sort of permissiveness to approach people for treatment. We haven't, as I say, seen a big step; it's been a gradual thing but one of the ideas that she [staff member who has written a research paper] put forward was that it might be that people would come forward more readily for treatment because they understood that people weren't going to be turned away when they might have been fearful of that before. Whether that makes a big difference in a clinic like ours when we were seeing them anyway a lot, I'm not sure...not a big difference... (Site 15, Doctor)*

As discussed at greater length previously, the acceptance of the need for a non-discriminatory approach co-existed with both reservations among some about the appropriateness of treating some single women, and accounts of the need to engage the patient in particular sorts of discussions about parenthood and its perceived demands. Descriptions of interpretations and understandings of what was meant by replacing 'the need for a father' with 'the need for supportive parenting' also in some cases reflected this perspective. For example in this case, it was explained that the legal change had made little difference as lesbian couples and single women were treated previously, and in any case, the same sorts of discussions with such patients were still taking place, about the need for a 'male figure'.

*I don't know that it's made any difference here, we've always treated a lot of same-sex couples and so that's always something that gets talked to them anyway...maybe if they've got a, you know, a male figure in their life somewhere that a child could relate to so that's something we've...we've always considered anyway so not necessarily a father as such because we've treated those couples but...and I think it...I think it's probably made it easier for same-sex couples, actually, to...to access treatment. And single women, we've always treated single women as well. Not as many, but we have treated some and...and obviously it's something that's talked about with them, about whatever male figure there may be that again, a child can relate to. (Site 12, PR)*

Insofar as respondents indicated they had a view on what 'supportive parenting' is (which many did not), the clearest opinion was that it would apply to same-sex couples and single women, perhaps because it was considered to be a direct replacement for the old wording that explicitly categorised these two groups as requiring additional input regarding their future parenting:

*...because I do start to ask them about social supports and their networks and those kind of things and I explain to them and that in those terms and say, you know, 'We're...we're obliged to think about the welfare of the child and...' and so supportive parenting is a term I use because it's the term...it's a political term. (Site 15, Doctor)*

*I don't think it made...the need for sort of supportive parenting, I think, in practice doesn't make a huge, huge difference to that. I really don't. I think the...we still will ask about the...whether there's a male role model, not as a father figure but just to be around just so that a boy would have an...an idea of that. But I think with the increasing publications that suggest that kids do perfectly well in same-sex couples, they're perfectly happy, adjusted and well balanced. On the harm side of things, I think that's just sort of, from our point of view, is almost again, this may be my own...own view, but it's almost just...almost confirming what we would have picked up...picked up on anyway. (Site 6, Doctor)*

*I don't think it's a term that's used commonly...I mean I talk more probably about family support and what input would you have, you know what level of input are you going to have from parents, siblings, probably rather than put it as supportive parenting. I will always say you know: are you planning this, is there anybody else going to be involved in their lives. (Site 13, Nurse)*

*I'm not sure what supportive parenting is...I think a male figure that...that a child might relate to because I think, well children don't...definitely relate differently to males and females and I think it is important that they are aware of the...the differences and the different relationships that might develop and the communication, I think, is often different with men and women for a child...maybe supportive parenting's not the right word. It's almost like supportive...Yeah. I don't know. Maybe it is the right word because I don't know what other term there would be but it's upbringing of the child, isn't it, and recognising that if... if it's a single woman or a same-sex couple that...that to give a child an all-round life experience and whatever else that they need to be aware of the role of men in society and relationships, I guess. (Site 12, PR)*

*...usually it's about support networks so say for a single woman they may say, 'Oh...' you know, 'she lives with a... she lives with her brother, very supportive family'. You know, 'She's financially stable...They'll talk about, you know, all the different things you'd obviously...because usually, I think, with a lot younger women, they come through as single parents so we usually ask them to think about it and come back, and see them in a few years because you think, you might meet someone. (Site 15, Embryologist)*

*I think it's always been about supportive parenting, really, because you can...you can have a partner or a father which is absolutely no use anyway, can't you, in a sense quite often and so it is whether there is support there in a lot of cases anyway...So perhaps not the actual phrase 'supportive parenting' but I think it's what we all look at. (Site 18, Nurse)*

The overall impression given by respondents was that the framework for assessment can be interpreted in various ways; it can be seen as both an attempt to *narrow* the parameters of assessment to a risk assessment of serious harm or neglect, but the definition of 'supportive parenting' can be interpreted in a *flexible* way, as 'health, wellbeing and development' of the child.

### **5.57 Is the welfare of the child assessment worthwhile?**

Previous iterations of the law, the HFEA code of practice and its guidance notes are not simply over-written by new formulations, but old interpretations and meanings can persist, coexisting with the new. We therefore asked interviewees about their own understandings of the meaningfulness of taking the welfare of the child into consideration, thinking about their professional life working in assisted conception services.

There was a notable ambiguity in the way that a large number of respondents expressed the view that requiring infertile couples to 'jump through hoops' in a way not expected of the fertile was inherently unfair, but all interviewees also felt that clinics had a responsibility for the future wellbeing of a potential child:

*Well I think we've got to make an assessment, but as I said, I think, you know, it is slightly unfair in the sense that, you know, not every parent has it so I think, you know, at the end of the day their consultant who sees the patients or whatever used to seeing, you know, patients all the time and I think, you know, they're perfectly, you know, able to sort of make that assessment and, you know, it's how long's a piece of string? You could go on forever like assessing every aspect of their life. You can't...I think it's quite minimal [the level of scrutiny]. (Site 13, Embryologist)*

*R: I don't know how it could be improved, really...Because you can't...it's difficult in a way because a lot of people talk about 'playing God'...and, you know, people can go and pregnant on their own or people who can go and get pregnant on their own don't have to go through all this. We do sometimes have people sort of say, 'Well...' you know, 'What are...what are you... why are you looking into this so much?'...But we just say to them, 'Well because we have to.*

*Because if we are seen to help somebody get pregnant who can't cope with it, then...' you know, 'We have a responsibility towards the child'.*

*I: And so do you think that the welfare of the child requirement serves an ongoing useful purpose?*

*R: Yes. (Site 18, Nurse)*

This embryologist expressed both the unfairness but also the inherent difficulty of making an assessment preconception.

*R: I think you always have to consider, you know, the welfare of any child but I don't know whether it's such an artificial situation because we're assessing parents before they've become parents so just basically because they have got an infertility problem where any other parents don't have this sort of type of assessment but I suppose because we are in that position of creating that child, do we create it into a bad life? But it's difficult. An old boss of mine always used to say like any life is better than...you know, no life at all. I know...you know, it's...it's a hard one to answer.*

*I: Do you think it's unfair in that sense?*

*R: Yeah I do. Yeah...But I think we also have a responsibility to a certain extent. (Site 13, Embryologist)*

These views are also echoed here by a Person Responsible:

*I honestly think that we probably catch...catch is the wrong word. Probably capture I don't know, five, ten per cent of the actual risk and the argument that the patient groups always used to make when this was a big issue was, 'Well...' you know, 'You can have a natural conception and nobody's checking on the welfare of the child etc. Who are...Why have you? What gives you the right to...to check?' and I think to a certain degree that...that there might be something to that. You know, maybe we shouldn't actually be...be checking because we can't guarantee that we're getting everybody. I'm sure there are children who were born into relationships and from assisted conception that are treated very badly but we can't see the future either, so... (Site 18, PR)*

All respondents reported they considered the basis on which any judgement could be made was limited, for example:

*I: And did you feel confident about assessing the risk as it's defined in the HFEA guidance?*

*R: Probably not...Because the difficulties in obtaining the relevant information. I'm confident that our nurses can identify and pick up areas of concern. What I'm not confident about is whether we can ever establish enough evidence to deny treatment where it should be...confident, and I think the competency of the environment will identify cases which are potential problems. What I'm not confident or competent about is...I'm not confident that we could in most cases derive sufficient, strong evidence to result in denying treatment. (Site 4, Doctor 2)*

*I think I can do a good job by listening to people and to extract information from them that might well be the sort of information that you could use objectively...Whether the decisions that we've made...we're advised through the ethics committee are still valid 20 years later, I would love to know that. Have we made some mistakes and that, I don't know and that would be lovely to be able to get that information but we've thought about this in our ethics committee; how do we get feedback from those that we've decided to treat when we've...we've had a concern about it and we decided there's really no information that we can...where we could get that information. (Site 5, Doctor 2).*

This nurse thought that the act of getting couples themselves to consider the welfare of the child was worthwhile:

*R: I can't think of a better system where you would be 100 per cent confident in that you would get all the right information about people and I'm not sure we should...I think probably because I've been in this place a long time, you kind of just accept that this is what we have to do and I think we do it quite well and this is the best way to do it. If it's talking me personally*

*whether I agree with it or not, I actually think I do agree with it um...I don't like this bit about being intrusive and asking GPs as much sometimes but I think it's good for a couple. It makes them stop and think and that's what's a positive about it that I have sat in with couples and I'm doing a nurse consultation and you have conversations about this and it does make them stop and think about 'oh well we've done this in the past' and they say 'aaaaarh', people say 'well I was a drug user but I wanted to be you know with them, we've got together, we want to be parents and we've stopped it because we thought this'...I don't know, I think there is positives with it.*

*I: And does the form prompt that?*

*R: I think it's the form...because people don't know about the form often until they get here and then they think...and I have had people say it's actually good and it's reassuring that we know as a clinic that you're bothered about these things. I've had the other side of it where people go: this is not right and we shouldn't have to fill in this because every Tom, Dick and Harry is getting pregnant, so you can see it from two sides really. Some people feel really assured that we're bothered...so I tend to come at it from that angle really that we are bothered and yes it can be intrusive sometimes but we as professionals if we are helping you to do this have to take some responsibility. (Site 13, Nurse)*

According to this Embryologist, it was sometimes difficult for staff to consider both the needs of the patient and the needs of the future child:

*I don't think we'd ever feel 100 per cent confident about that just because it's so... we're relying so much on either people flagging something up to us or us noticing so I think...and as we've said before, I think if somebody desperately wanted to hide something if the GP or someone didn't mention it and they desperately wanted to hide it, they probably could...I think we would all be devastated if further down the line something awful happened to a baby that had been born here as a result of treatment. I think we would all be devastated because we...we're probably living in this rosy coloured...rose coloured glasses sort of situation of, you know, all these people desperately want to have children and we can help them and do you know what I mean? So I think...I think we would be really, really devastated and I think that is always in the back of our mind when we're looking...talking about the cases, particularly the ones that go to the management meeting is that we...we are intervening and so we can choose to intervene or not. So it is...that is something that we take very seriously, but on the same token we get so involved with the couples that sometimes it's hard to see beyond the couple you've got in front of you...and I think that's difficult because actually you do have to be able to separate the two and if it's not right for the...the child, then you have to ignore the emotions that are coming at you from the couple, which is really hard. It's really hard because at the end of the day the couple are in front of you and you can see them and talk to them and the child isn't. (Site 6, Embryologist)*

This embryologist expressed clearly the role of the HFEA in balancing patient interests with the views of the general public:

*I think my personal opinion is that the HFEA have quite a tough job between sort of satisfying clinics and satisfying public opinion and safeguarding sort of patients, acting in their best interests and I think it's quite a fine, delicate balancing act trying to satisfy all...and you're never going to please everybody. But I do think that the current code of practice is probably prescriptive enough to sort of make sure that people aren't refusing treatment on the basis of hunches and sort of...there is no sort of room for discrimination there but also allows clinics to use their judgement and I think...hope...I do feel that the act does achieve that. It has some ability to use your sort of own judgement and also it means that people can't completely sort of run away with this and just select which...cherry-pick which patients they want to pick. (Site 5, Embryologist)*

This nurse states that it is important for clinics to be seen to take the welfare of the child seriously:

*I don't think you can ever be 100 per cent, you know, sure that what you're doing is not bringing any child...couldn't bring any child into danger in the future but I think you have to be seen to be doing something and at least we're doing something...I mean you could take it to the extreme or... but I, you know, I don't think that's feasible or, you know, sort of financially*

*feasible, let alone even in an NHS unit, you know, or anything. So I think, you know, I think the fact that you're doing something shows that you're...you are taking the welfare of the child into sort of consideration. (Site 9, Nurse)*

Some professionals distinguished between considering the welfare of the child as part of exercising clinical responsibility, and the formal requirement to prove that such a consideration had taken place:

*I think that the actual box-ticking is probably box-ticking but the idea behind it is quite...is definitely right and proper and I think it's up to...my view would be that it's up to the individual clinic to decide how they comply with the...principle...as in all medicine, as they, you know, how they comply with the...the guidance and with their own processes, rather than just go through this. I mean just because you've ticked those boxes it doesn't mean anything at all. I hate guidelines; I hate the tick-boxes and in all of medicine. What really matters is whether you are applying the...good practice principles. Unfortunately, I think many people do think it is a ticking-box exercise. (Site 5, Doctor 2)*

*R: I think we have a responsibility to the couples that are seeking treatment to any children born as a result of treatment and we also have a responsibility to society as a whole, particularly when we're accessing public funding for patients, so I think we have a responsibility there. How far that goes as to us assessing who should be a parent or not, that's a different issue but if we have concerns then I think it's our responsibility to raise those, just as we would if we saw something...an incident happening in the street. We ought to be able to alert someone.*

*I: And do you feel fairly confident that there are things in place? I mean you can pursue that with them?*

*R: Oh definitely. Definitely to pursue those but whether or not they would always get picked up is another issue... (Site 12, PR)*

*I personally feel very confident. Why? Because, you know, you are interacting with human being and you are seeing them more than once and in your dealings and interaction with them, you can get an idea about whether this is functional unit, dysfunctional unit, the guy is having this, having that. I mean it just really...I... I can't see that being difficult...Yes. You feel confident because if you have the experience and you've been doing that for 20 years and you have seen couples in different arrangements and everything you feel confident and competent to do that. And also you will always be supported by the knowledge that you...there is a structure within the unit that you work in to help with these issues. Whether it is a counsellor, whether it is a team, whether it's yourself, so the whole process is comprehensive...Whenever we are coming across unusual scenarios, it's shared so you accumulate. It's not just the cases that you see, but the cases of other people...I think we...we have a great responsibility as embryologists. We're the people who are inseminating. We're creating embryos and therefore if there are any concerns, we tend to have...yeah, very, very strong views, you know; well-informed, educated views on whether we...we think that should proceed and, like I say, we have this...always a possibility a conscientious objection to pull out of the cycle. (Site 9, Embryologist)*

*I think there needs to be some attempt I suppose...I think there needs to be some attempt to consider the welfare of the child and it's good that we've got this because it focuses the mind a little bit, but I don't pretend that it's reliable...I think as it is it's OK at the moment. I think at the moment it's okay and you can't because to make it more searching or more whatever no I think it's okay the way that it is and I wouldn't like to go back to the way it was. (Site 1, PR)*

*...at the sort of operational level, I would say we still talk about welfare of the child and we still talk about good medical practice...you know, thankfully because I think that's what trumps everything I hope. So no, supportive parenting it's like...I mean if someone, you know, if a lay person engaged me in a conversation, I probably wouldn't use the term 'supportive parenting'. I'd say...I'd probably say, which means the same thing, you know, 'this is all about making sure that the parents can do the job and look after the child properly'. You know, which is kind of supportive parenting and I would argue, even though, you know, I'm a father and I think I have a role and it's... it's linked to being male in some respects, but not necessarily but I would definitely say there's a lot of evidence now that you don't need a father. Just because*

*I'm a father, I wouldn't...you know, I'm objective enough to do that. But no, I don't think people really use this sort of jargon and do you know another thing is we have a...in this field, we have a huge amount to try and keep up with and that's not...I'm not crying about it, but technologically, regulation-wise, you know, it's a very shifting thing and it's quite hard to keep up with the whole...and things like this where maybe they're taken seriously but because they're taken seriously anyway, I mean it's frankly it's sort of legal battle and sometimes seen as that. (Site 8, PR)*



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# Appendices

## Appendix 1: In Principle Letter (sent to Person Responsible at each clinic)

I am writing to you as Person Responsible to enquire whether you would be interested in your clinic participating in research into Welfare of the Child assessments.

The project is led by experienced researchers in social policy and law at the University of Kent, in consultation with an Advisory Group, comprising clinician Mr John Parsons; Clinical Embryologist, Dr Alan Thornhill; research scientist Professor Geraldine Hartshorne; Professor of Law, Gillian Douglas; Dr Kirsty Horsey of BioNews; Sarah Norcross of Progress Educational Trust, Professor of Social Work, Eric Blyth; Senior Infertility Counsellor, Jennie Hunt, and members of Infertility Network UK. The study is funded by the Economic and Social Research Council (ESRC) and is awaiting confirmation of NIHR portfolio status.

Our focus is to understand how current HFEA 'Welfare of the Child' guidance operates 'on the ground' in UK clinics, and what effects (if any) the changes to the Human Fertilisation and Embryology Act have caused. We do not wish to evaluate practitioners, but we want to find out what clinic staff think about the new Welfare of the Child arrangements. To this end, we wish to conduct **semi-structured interviews to explore the views of clinicians, counsellors, embryologists and nursing staff**. We aim to interview staff at a quarter of all clinics in the UK and our aim is for the sample to reflect the diversity of the sector.

We hope that we can work with you and your colleagues to find a convenient time and place for a face-to-face interview lasting around one hour with four members of your team, one for each of the four staff groups mentioned. We fully understand that finding a spare hour will be challenging for busy clinic staff; however, we will work around your schedule and if you prefer a telephone or skype interview, this may be an alternative in certain circumstances. To demonstrate our appreciation we will provide a Certificate of Participation to all interviewees, useful for documenting Continuing Professional Development, and we will invite all participants to our educational dissemination event at the end of the study.

We will be in contact shortly to find out if you are interested in taking part. In the meantime, if you have any queries or prefer to respond directly, please email [E.J.Lee@Kent.ac.uk](mailto:E.J.Lee@Kent.ac.uk) or call Dr Lee on 01227 827526.

Thank you for taking the time to read this letter, and for your consideration of our request.

Yours sincerely,

Dr Ellie Lee,

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## Appendix 2: Participant Invitation Letter (sent to all potential participants)

Name of potential participant  
Clinic Address

Dear [Name of potential participant] [Clinician, Nurse, Counsellor or Embryologist, NOT Person Responsible]

We are writing to invite you to take part in a research project entitled **Assessing Child Welfare under the Human Fertilisation and Embryology Act: The New Law**. The study is being conducted by researchers in Social Policy and Law at the University of Kent and is funded by the Economic and Social Research Council.

Your clinic was selected as part of a representative sample of UK fertility clinics and ....., as Person Responsible has agreed to participate. We will therefore be seeking to interview four people at [name of clinic], a Clinician, a Nurse, a Counsellor and an Embryologist. We would be grateful if you would agree to take part. It is, however, entirely up to you to decide whether to join the study. Further information about the study is contained in the attached Information Sheet.

My colleague Dr Jan Macvarish will be in touch shortly, but in the mean time, please do not hesitate to contact me with any queries via email [E.J.Lee@Kent.ac.uk](mailto:E.J.Lee@Kent.ac.uk) or by telephone 01227 827526.

Yours sincerely,

Dr Ellie Lee

## **Appendix 3: Information Sheet for Participants**

### **INFORMATION ABOUT THE RESEARCH**

#### **Assessing Child Welfare under the Human Fertilisation and Embryology Act: the New Law**

We would like to invite you to take part in our research study. Before you decide, we would like you to understand why the research is being done and what it would involve. One of our team will go through the information sheet with you and answer any questions you have. Part 1 tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study. Talk to others about the study if you wish. Please ask us if there is anything that is not clear.

#### **Part 1**

##### **Information about the study**

The focus of the study will be to understand how the 2008 changes to the Child Welfare Assessment in the Human Fertilisation and Embryology Act (1990) and the subsequent HFEA guidance are operating across UK clinics. We intend to interview staff at a quarter of all clinics in the UK and our aim is for the sample to reflect the diversity of the sector.

The project is led by experienced researchers in social policy and law at the University of Kent, in consultation with an Advisory Group, comprising Clinician Mr John Parsons, Clinical Embryologist, Dr Alan Thornhill; research scientist Professor Geraldine Hartshorne; Professor of Law, Gillian Douglas; Dr Kirsty Horsey of BioNews; Sarah Norcross of Progress Educational Trust, Professor of Social Work, Eric Blyth; Senior Infertility Counsellor, Jennie Hunt, and members of Infertility Network UK. The study is funded by the Economic and Social Research Council (ESRC).

##### **The purpose of the study**

The purpose of the study is to get an accurate picture from across the UK fertility sector of how the new law and guidance are working out in practice. The aim is not to evaluate practitioners but to find out what clinicians and other clinic staff (for example, nurses, counsellors and embryologists) think about how the new arrangements compare to the previous framework; what problems have been resolved, what problems still exist or what new problems have been thrown up.

##### **Why you have been invited**

Your clinic was selected as part of a representative sample of UK Clinics and the Person Responsible has agreed to participate. We will therefore be seeking to interview four people at your clinic and would be grateful if you would agree to be one of them.

##### **Do I have to take part?**

It is entirely up to you to decide whether to join the study and you are free to withdraw at any time, without giving a reason. Before you make a decision, we will describe the study and go through this information sheet. If you agree to take part, we will then ask you to sign a consent form. You will be given a copy of the signed consent form and this information sheet to keep.

##### **What will be involved?**

Your participation will involve taking part in a single confidential, face-to-face interview with one of our researchers, on clinic premises and during working hours. The interview would last approximately 60 minutes and would be recorded (with your permission) on a digital recorder so that your responses can be transcribed for inclusion in our analysis.

## **What questions will be asked during the interview?**

These are some of the themes and questions we would like to ask you about in the interview:

- How does the assessment of prospective patients operate at your clinic?
- What are the bases for exclusion from treatment according to your clinic's interpretation of the welfare assessment?
- What is the information-gathering and decision-making process by which patients are assessed regarding the welfare of the child and accepted for, or excluded from, treatment?

We may invite you to provide examples from individual case histories, but we recognize that you would be obliged to present this data in such a way that individual patients are not identifiable. We will also ensure that no patient is identifiable in the transcript or in any subsequent publication arising from the study.

### **Confidentiality**

Clinicians and other clinic staff will not be identifiable in the transcribed interview and will be pseudonymised in any resulting publications. The size of the respondent group is sufficiently large to ensure that confidentiality can be maintained.

### **Possible benefits to taking part**

At the end of the research, we will send all participants a copy of the final project report and all participants will be invited to attend an event to discuss the findings with those involved in making policy in this area.

## **Part 2**

### **Confidentiality**

Your responses will be totally confidential. The transcript of the interview will be coded and anonymised so that neither you or your clinic will be identifiable, except to the three members of the research team. Transcription will be carried out by a transcriber employed at the University, who will be required to operate to the University's standards of data protection. The digital recordings of the interviews will be transferred to a password-protected computer and deleted once transcription has taken place. Interview transcripts will be stored in a locked filing cabinet on university premises with access only available to the named staff involved in this project. Data will be retained by the research team for 18 months and will be disposed of securely. In line with the policy of the project's funder, the ESRC, fully anonymised data may be made available to other researchers on the Economic and Social Data Service database (ESDS) and will be retained there for a period dictated by the ESRC. Access to view identifiable data may be granted to authorised staff for audit purposes

### **Use of quotations**

In the event of the researchers using direct quotations from the interviews in project reports or publications, any details which may potentially identify the interviewee or the clinic will be removed.

### **How poor practice issues that may be revealed will be dealt with**

We do not wish to evaluate practitioners; we want to find out what clinic staff think about the new Welfare of the Child arrangements. However, our research ethics framework requires that in the unlikely event of poor practice issues arising, we would be obliged to raise any concerns with our Advisory Group.

### **Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Oxfordshire REC B Research Ethics Committee. The project has been reviewed for academic merit by the University's own internal peer review process and by the Economic and Social Research Council's review prior to funding being granted. The project will be conducted in accordance with Kent University's policy and the Socio-Legal Studies Association's research ethics policy. The project has

obtained approval from the Kent University Research Ethics Committee, from Oxfordshire REC B NHS Research Ethics Committee and, in line with NHS policy, from the Primary Care Trust Research and Development office for each NHS clinic (approval has also been gained from the relevant body for each private clinic).

### **Who is organizing and funding the research?**

The study is funded by the Economic and Social Research Council and is organized by University of Kent researchers from the School of Social Policy, Sociology and Social Research, the Centre for Health Services Studies and Kent Law School.

### **Further information and contact details**

If you would like any further information about the study, please contact the Principal Investigator, Dr Ellie Lee, Senior Lecturer, School of Social Policy, Sociology and Social Research, University of Kent, Canterbury, Kent, CT2 7NF, 01227 827526, [E.J.Lee@Kent.ac.uk](mailto:E.J.Lee@Kent.ac.uk)

### **Complaints should be addressed to:**

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. Please contact Dr Ellie Lee on 01227 827526 or email [E.J.Lee@Kent.ac.uk](mailto:E.J.Lee@Kent.ac.uk). If you remain unhappy and wish to complain formally, you can contact the University of Kent's Acting Director of Research Services, Dr Kathy Bennett, Room Reg 154, The Registry, [K.L.Bennett@kent.ac.uk](mailto:K.L.Bennett@kent.ac.uk), who will conduct an investigation and respond.

## Appendix 4: Topic Guide

### Assessing Child Welfare under the Human Fertilisation and Embryology Act: the New Law

#### Topic Guide

##### Section 1: The route to treatment

**This section of the interview will ask about how prospective patients access treatment, and where and how routine welfare of the child assessment takes place as part of this.**

1. Who do prospective patients first see when they come to your clinic?

PROBE

What are the main aims of the first consultation session, where does the welfare assessment fit into this?

At what point are patients given the Welfare Assessment form?

What other consultations might a prospective patient have before treatment begins?

2. To what extent, and on what grounds, might prospective patients be excluded before they arrive at the clinic (e.g. through NHS funding criteria)

Do you think some patients might be deterred from pursuing treatment because of the initial screening/assessment process?

3. At your clinic, how does the welfare of the child assessment take place?

PROBE

Are prospective patients provided with the HFEA leaflet on Welfare of the Child Assessments?

Do you provide any other information on this aspect of the process? [Ask for copies]

Is any information provided prior to consultation? [Ask for copies]

Do prospective patients fill in the HFEA patient history form?

If so, how do they return it and who reviews the information provided?

If so, and no 'yes' boxes are ticked, will the prospective patient always move to the next stage?

If the HFEA form is not used, how is information relevant to welfare of the child assessments obtained and reviewed?

Is the routine procedure any different depending on treatment sought? (Specifically, ask about patients seek to use donor gametes, intra-familial gamete donation, and surrogacy)

4. What is the procedure for patients seeking treatment using:

-donor gametes-intra-familial gamete

-donation and surrogacy

-egg-sharing?

##### Section 2: Welfare of the child concerns

**This section of the interview will ask about instances where prospective patients are considered to present potential child welfare concerns.**

1. The HFEA patient information form raises the following as possible reasons as to why a child yet to be born may be likely to be at risk of serious harm:

- Previous convictions relating to harming children
- Child protection measures taken regarding your children
- Serious violence or discord within your family environment
- Physical or psychiatric illnesses
- Increased risk of any transmissible or inherited disorders
- Drug or alcohol problems



Can you comment on what you think should happen if a prospective patient answers 'yes' to any of the above?

PROBE

Discuss one by one and explore

2. What, if any, role should counselling play in relation to welfare of the child assessments?

PROBE

Is it compulsory for any of your patients to go through counselling ?

Do you have concerns about the purpose and usefulness of counselling being affected where counselling is used as part of welfare of the child assessments?

Would it be better if more clients had a session with the clinic counsellor?

Where clients in general opt to see the clinic counsellor, what are the benefits?

3. Over the past two years, how many instances have there been, in your clinic, where a prospective patient has been considered of concern on welfare of the child grounds? *(If possible, aim to obtain fully anonymised, factual information on the basis of clinic records.)*

Can you give me some examples of the kinds of issues that raised concern and how these were dealt with?

4. Over the past two years, how many instances have there been where a prospective patient has been denied treatment on welfare of the child grounds? *(If possible, aim to obtain fully anonymised, factual information on the basis of clinic records.)*

PROBE

Are such patients usually directly 'denied' treatment or might they be referred elsewhere or their treatment deferred?

6. Do you feel confident about assessing risk, as now defined, in the way provided for by the HFEA guidance?

Do you feel competent in assessing risk? PROBE Have you received any training?

Does your clinic ever seek external, expert guidance or assessment, for example from an Independent Social Worker?

7. What weight would you attach to the following, which are not raised specifically in HFEA guidance?

- Age of either parent
- 2 gay men or 2 lesbians
- A single man
- Other types of relationship status (particularly where there may be multiple partners, or two individuals who are not in an intimate relationship seeking treatment together)?
- How do you administer the 'Agreed Fatherhood Conditions'
- Transgender status
- Clinical obesity
- Serious illness
- Other?

PROBE

*In consultation with the Advisory Group, scenarios and hypothetical case studies may be developed for use as part of the interview.* **Section 3: Views of the changes made to the welfare clause and accompanying guidance and its impact on the assessment process.**

**The aim of this section is to obtain views on whether the new legislation and current HFEA guidance provides an appropriate regulatory framework.**

In 2008, section 13.5 of the statute regulating fertility treatment was amended. It now states,

*A woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for supportive parenting), and of any other child who may be affected by the birth.*

In 2005, the HFEA provided new guidance for clinics on interpreting the law, and it states in the HFEA leaflet for patients that, *'there is now a presumption to provide treatment, unless there is evidence that the child is likely to experience serious harm'*.

In this light:

1. Thinking about the 2005 guidance, what effects has this had on what the clinic does?

PROBE

Do you believe that the changes made to the guidance have solved the problems previously associated with welfare assessments?

PROBE

Does it provide a basis for common standards between clinics, addressing inequity in access to services?

Does the HFEA guidance allow clinicians/clinic staff to feel confident about what they are doing?

2. What has changed since 2008 specifically:

PROBE did the changes ensue from 2005 rather than 2008?

What have been the effects of removing the requirement to consider the 'need for a father'?

How does the clinic deal with the HFEA guidance that Donor Insemination couples tell the child of the method of their conception?

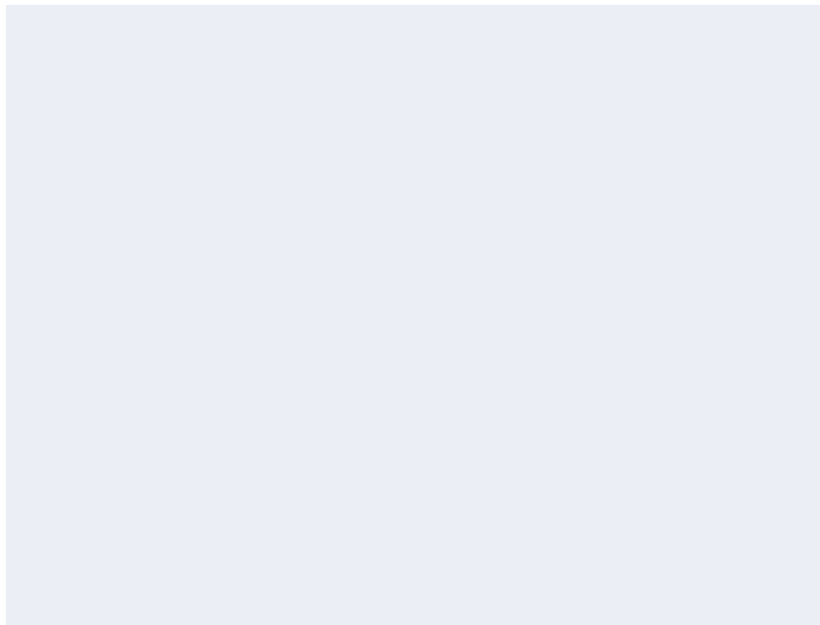
3. How is the phrase 'supportive parenting' (as used in the 2008 law) understood by clinic staff?

3. Does the legislation now establish an appropriate regulatory framework in this area?

PROBE

Does the legal requirement to take into account the welfare of the child serve any ongoing useful purpose?

**[END]**



For more information about this study, and the work of the  
Centre for Parenting Culture Studies, see:  
<http://blogs.kent.ac.uk/parentingculturestudies/>

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