BPAS investigation into the IVF postcode lottery: an examination of CCG policy for the provision of fertility services

BPAS fertility

Introduction

In England fertility services, including in vitro fertilisation (IVF), are provided by a mixture of NHS and private services, with roughly 35% of treatments funded by the NHS – the lowest of all four UK nations (HFEA, 2020).

Responsibility for commissioning fertility services in England is taken by Clinical Commissioning Groups (CCGs), which were created following the 2012 Health and Social Act (replacing Primary Care Trusts). CCGs are statutory NHS bodies which plan and commission services for their local area, including community care, emergency care and mental health services. CCGs are independent, and accountable to the Secretary of State for Health and Social Care via NHS England. At present there are 135 CCGs in England (following a recent restructure in which several were merged).

Guidance for how fertility services should be commissioned and provided is issued by the National Institute for Health and Care Excellence (NICE). Recommendations are made by NICE on the basis of both clinical and cost effectiveness (McCabe et al., 2008). CCGs do not have a statutory obligation to comply with NICE clinical guidelines (unlike NICE technology appraisals which must be implemented), but nonetheless test cases have confirmed that CCGs should not disregard NICE guidelines unless there is a clear clinical case for doing so (NICE, 2014a).

The most recent NICE clinical guideline for fertility treatment (CG156) was issued in 2013 and determined that IVF is cost effective up to age 43 (NICE, 2013; Kmietowicz, 2012). This assessment was made following an economic analysis that considered quality adjusted life years (QALYs), cumulative success rates across clinical settings, single and double embryo transfers, and a background chance of conceiving naturally (Kmietowicz, 2012).

However, the extent to which CCGs follow this guidance is varied. Differences between individual CCGs' policies in England has led to the emergence of significant regional variation in fertility funding, dubbed the "IVF postcode lottery", which has been criticised by campaigners, professional bodies, the media and even the current Health and Social Care Secretary, Matt Hancock MP (NICE, 2014b; BioNews, 2016; RCOG, 2017; British Fertility Society, 2017; BBC News, 2017a; Fertility Fairness, 2018; Fertility Network, 2019; Evening Standard, 2019; Metro, 2019; inews, 2020; Huffpost, 2020; HSJ, 2020). A recent publication from the Human Fertilisation and Embryology Authority (HFEA) outlined that the proportion of NHS-funded IVF cycles has fallen across several English regions (HFEA, 2020).

This report examines the differences between CCGs' policies for fertility services in England, and outlines some of the key differences that affect patients depending on their postcode. It relates specifically to England, since fertility services elsewhere in the UK are commissioned through a different structure. In Scotland, all couples have access to three full cycles of IVF if they meet nationally agreed NHS criteria (BBC News, 2017b; National Infertility Group, 2016), while Wales and Northern Ireland each have a national policy that is more restrictive, offering two full cycles and one cycle respectively (Fertility Network, n.d.).

About BPAS

BPAS is a reproductive health charity that cares for around 100,000 patients a year for reproductive health services including pregnancy options counselling, miscarriage management, abortion care, STI testing and contraception. It also campaigns and advocates for access to evidence-based, patient-centred care. BPAS is the home of the Centre for Reproductive Research and Communication (CRRC), which has a mission to develop and deliver a research agenda that furthers patient access to evidence-based reproductive healthcare, driven by an understanding of patients' perspectives and needs. BPAS' research includes a two-year Wellcome-funded project called Wrisk, which seeks to understand and improve the communication of risk on issues relating to pregnancy. In August 2020, BPAS announced its plans to provide fertility services on a not-for-profit basis in the UK from 2021.

Objective

To outline and quantify key differences between CCGs' commissioning policies for fertility services in England.

Method

Freedom of Information (FOI) requests were submitted to all 135 CCGs in England between March and July 2020, to request a copy of their access policies for assisted conception services. Policies were analysed with reference to the number of IVF cycles offered, number of embryo transfers per cycle, female age limits, requirements for determining infertility, inclusivity for same-sex couples and single women, and other requirements regarding body mass index (BMI), smoking status and childlessness.

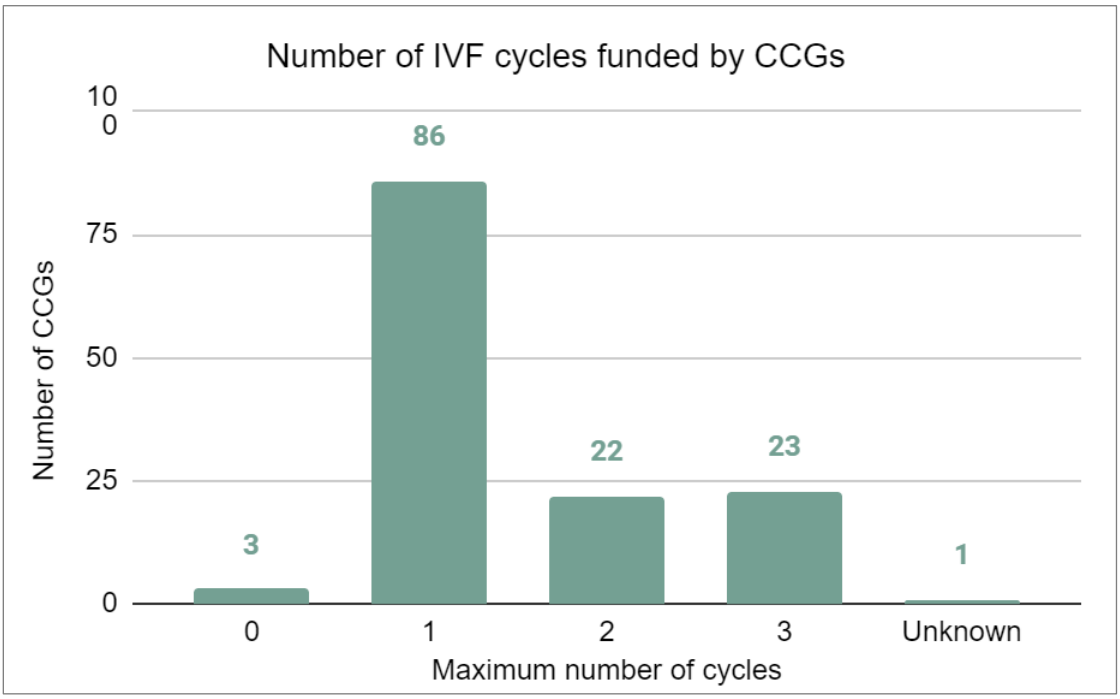
Results: Outline of key differences between CCG policies

1. Number of funded cycles

In its clinical guideline CG156, NICE recommends that women under 40 should be offered three full cycles of IVF, and those aged 40-42 should be offered one cycle (NICE, 2013 (1.11.1.3)).

However, when comparing the number of cycles of IVF available in different regions of England, the distinction between NICE guidance and local CCG policies is vast. Three CCGs in England do not provide any funding for IVF services, and one CCG had no policy in place at the time of writing. 131 CCGs specified a maximum number of cycles available: *108 (80% of all CCGs) fund fewer than the three cycles recommended by NICE*, with *86 of these (64% of CCGs) only*

funding one cycle of IVF per individual/couple. *Just 23 CCGs fund the three cycles recommended by NICE.*



Reducing the number of cycles available to patients is likely to be intended as a cost-saving measure by CCGs, which have a wide range of services to provide out of limited budgets. Nonetheless such a measure will inevitably reduce patients' chances of achieving a successful pregnancy. It is also likely to impact cost effectiveness: in its Quality Standard 73, NICE states that offering fewer than three cycles is unlikely to be cost effective based on a live birth rate per cycle of 28% (NICE, 2014e).

2. Definition of a cycle

NICE defines a full cycle of IVF treatment as "1 episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryo(s)" (NICE, 2013). This suggests that all embryos of suitable quality created from each IVF cycle should be available for use until an embryo transfer is successful in achieving a live birth or until no embryos remain.

For each funded cycle, the number of embryo transfers available is at the discretion of local CCG policy. In contradiction to NICE's definition of a cycle as the unlimited transfer of all suitable embryos, *only 55 CCGs (41%) allow for unlimited transfers, with 19 CCGs (14%) permitting only one embryo transfer per cycle.*

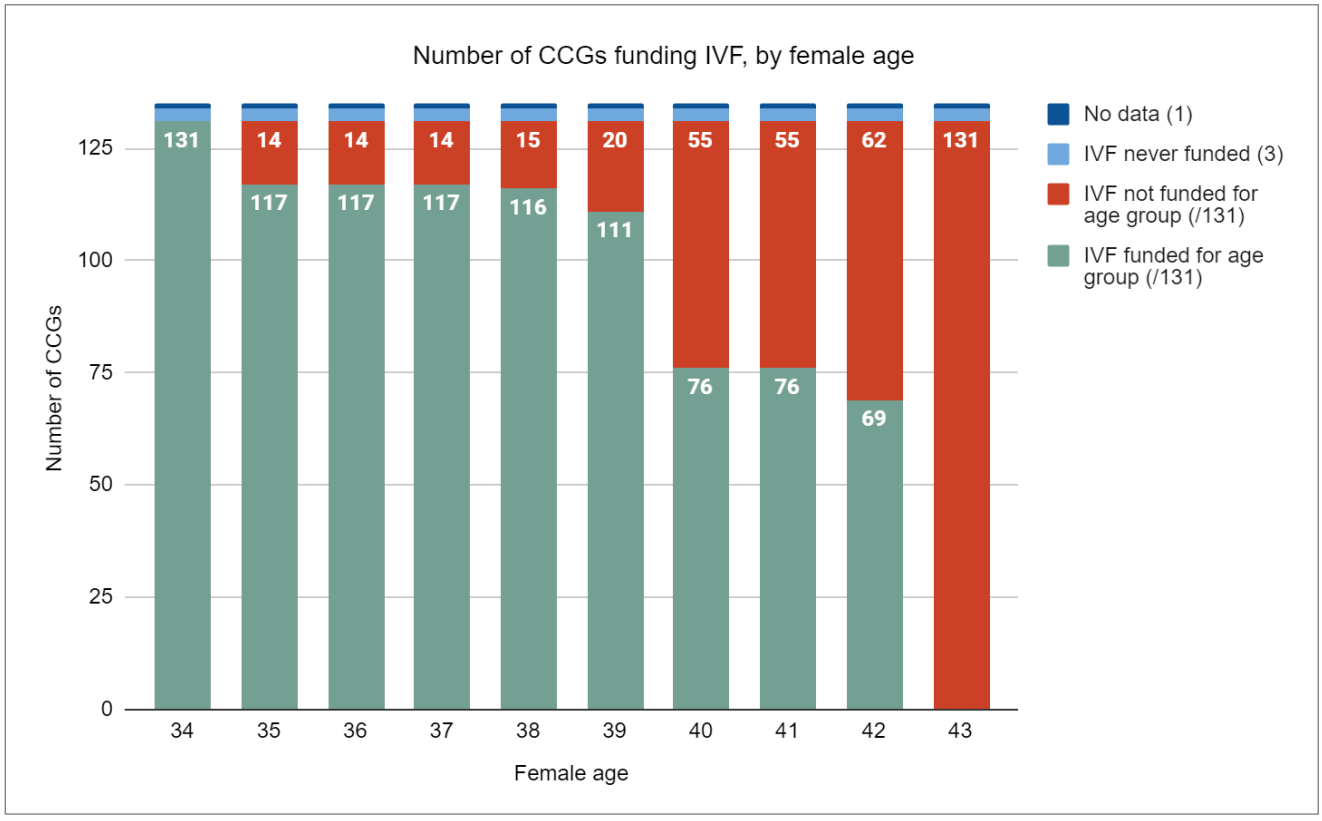
The availability of multiple embryo transfers per cycle is important in order to remove the incentive to transfer several embryos at once, which slightly increases the chance of a pregnancy but also leads to multiple births – the biggest health risk to both mothers and babies

from IVF (HFEA, 2020). The availability of multiple embryo transfers within a cycle also reduces the chance that women will have to undergo a subsequent full cycle of IVF to achieve a pregnancy, reducing their risk of ovarian hyperstimulation syndrome (OHSS) (HFEA, 2020; Smith et al., 2015).

3. Female age limits

The variability in age criteria adds to the discrepancy between areas. Alongside the 3 CCGs who do not offer funded fertility treatment, *55 CCGs do not offer any fertility treatment to women aged 40 or over*. This exclusion directly contradicts NICE's recommendation of prescribing 1 cycle of IVF for women aged 40-42.

Some of these 55 CCGs go further, excluding women at a much younger age. *14 of these CCGs only offer fertility services to women under the age of 35, and another 6 have female age cut-off points between 37 and 39.*



The restriction of IVF services to women of relatively young ages runs counter to a general trend in the population towards later motherhood, as more people choose to delay starting a family. Childbearing statistics published in 2019 revealed that women are starting their families slightly later than previous generations (ONS, 2019). Recent birth figures released by the Office of National Statistics showed an overall decline in fertility rates across England and Wales, but

women over 40 were the only group to buck this trend with a small increase (ONS, 2020). In this context, it is clear that CCG policies with low age limits are likely to be excluding a large cohort of patients who have not yet started or completed their families and who therefore may need access to fertility services.

4. Infertility status

IVF is not offered to patients without fertility problems, and therefore eligibility for IVF depends on the fertility status of an individual/couple. CCGs only refer individuals/couples to IVF services once their infertility has been verified. This verification criteria is dependent on the individual policy of each CCG.

An individual is considered to be infertile or sufficiently "sub-fertile" for referral if they a) have "explained infertility", where the individual has a diagnosed medical reason for infertility or b) have "unexplained infertility" but have been trying to conceive for a minimum period of time.

a. Explained infertility

For individuals/couples who have "explained infertility" this does not necessarily guarantee an immediate referral for IVF, and *3 CCGs specify that individuals/couples must wait a complete year for referral even when the cause of their infertility is known*. This waiting time for individuals who have a medical explanation for their infertility is effectively a pause in their treatment pathway, which only serves to add pressure to a situation that is already time-sensitive.

b. Unexplained infertility

For those with "unexplained infertility" (i.e. without a known medical cause), a time frame is also applied according to CCG policy. This varies depending on whether the individual/couple is trying to conceive through vaginal sexual intercourse or artificial insemination (AI).

For conception through vaginal sexual intercourse, NICE guidance suggests referral following 2 years of unexplained infertility. However, *16 CCGs (12%) require a period of at least 3 years of unprotected sexual intercourse before a couple is eligible for referral for IVF*. The additional year required by these CCGs exceeds the NICE guidance, and only serves to hinder fertility outcomes by postponing the beginning of the treatment process. Only one of these 16 CCGs specifies that the 3-year minimum can be reduced if the woman is above a certain age.

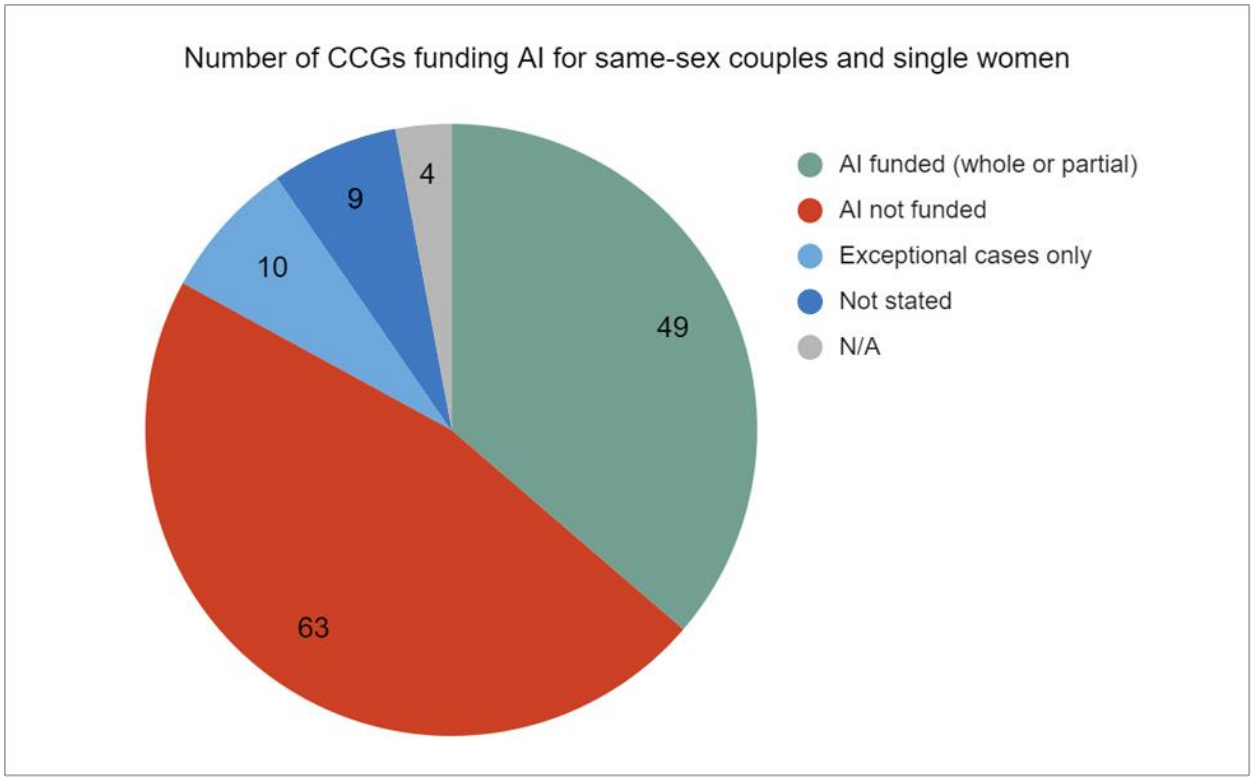
c. Artificial insemination

For patients who cannot conceive through vaginal sexual intercourse, artificial insemination (AI), often in the form or intrauterine insemination (IUI), is used to determine infertility. This sometimes applies to heterosexual couples for whom vaginal intercourse is difficult or impossible, but mostly it is a requirement of same-sex female couples and single women.

CCG policy requires single women or same-sex female couples to undergo 6-12 cycles of AI (of which 6 are often required to be IUI) before their infertility can be determined. This aligns with NICE guidance.

NICE does not specify a time period over which these cycles must be completed. In contrast, 27 CCGs (20%) detail a minimum length of time over which the cycles of AI must occur, effectively requiring patients to space out their AI cycles over a longer time period than necessary. *11 CCGs (8%) require a minimum of 3 years over which the AI cycles must be completed*, to align with the 3 years required of heterosexual couples having unprotected vaginal intercourse. Again, this long time period may hinder fertility outcomes by delaying the beginning of the IVF treatment process. No exceptions are made to account for the patient's age.

Artificial insemination is a costly process, averaging between £350 - £1000 per cycle, and access to AI funding varies across England (HFEA, 2018a). 49 CCGs (36%) do provide some funding for AI, but individuals/couples are often still expected to fund a proportion of this treatment themselves. *73 CCGs (54%) do not routinely contribute any funding to patients who must undertake AI in order to verify their infertility.*



The requirement that patients should self-fund all cycles of AI conflicts with NICE guidance which recommends that CCGs should fund at least 6 cycles of IUI. The financial burden of self-funding AI is likely to present a *significant additional barrier to IVF access that disproportionately affects single women and same-sex female couples*. Additionally, the live birth rates for AI and

IUI treatments per cycle are around half that of IVF, and also lower than normal conception rates – placing single women and same-sex couples at further disadvantage (HFEA, 2018b; Taylor, 2003; HFEA, 2020).

5. Inclusivity: same-sex couples and single women

The majority of policies have been recently modified to include female same-sex couples within their regulations. Out of 135 CCGs, 122 policies state that female same-sex couples are eligible for the same number of NHS-funded cycles of IVF and embryo transfers per cycle as heterosexual couples. 9 CCGs do not reference the provision of IVF for female same-sex couples in their policies.

Access to tertiary fertility services is however less clear in the case of single women. Although 70 CCGs (52%) state that they extend access to IVF services to single women, *7 CCGs explicitly say that IVF provision does not extend to single women and is limited to couples and 4 say that single women can only access treatment in exceptional circumstances*. 50 CCGs make no reference to single women. In these cases, anecdotal evidence suggests that in practice IVF is not accessible without a partner.

Additionally, relationship clauses also serve to exclude single women from accessing services. *24 CCGs strongly imply that single women are excluded through stipulations that patients must be in a "stable relationship".* This is defined in most cases by longevity, with CCGs specifying that couples should have been together for at least two years. However, some CCGs also include additional relationship criteria such as long-term cohabiting (in one case to be evidenced with utility bills or bank statements) or being "financially interdependent".

6. Body Mass Index (BMI)

BMI criteria exist across almost all CCGs in England, with *130 CCGs (96%) specifying a maximum female BMI* and 114 (84%) also specifying a minimum. The required female BMI values range between 19km/m² and 29 - 30km/m². In all cases, if a woman's BMI lies outside the specified range, the patient will be denied access to tertiary fertility treatment.

For male partners, 32 CCGs (24%) detail a maximum male BMI, with required BMI values ranging between 19km/m² and 35km/m². If a man's BMI lies outside the specified range, the couple will be denied access to tertiary fertility treatment.

The denial of treatment based on either female or male BMI constitutes an extension beyond the NICE guidance, which only recommends that men and women "should be informed" of the risks to infertility associated with obesity or low body weight in women and obesity in men. The extent to which IVF outcomes are impacted by a higher BMI is somewhat controversial: some studies have found that a higher BMI is associated with impaired ovarian responsiveness and/or

an increased risk of miscarriage, preterm delivery, or certain conditions including gestational diabetes, but others have concluded that a higher BMI should not be a basis for treatment denial (Friedler et al., 2017; Kasum et al., 2018; Ozgur et al., 2019). Certainly NICE does not recommend that fertility treatment is withheld on the basis of BMI, but only that women should be informed that female BMI should ideally be in the range 19–30 before commencing assisted reproduction, and that a female BMI outside this range is likely to reduce the chance of success.

Four CCG policies also require that BMI must be maintained for the previous 6 months before referral. The use of a minimum time period presents a further barrier to IVF access. The NICE guidance neither recommends the denial of fertility treatment based on BMI nor a minimum time period for BMI maintenance. These additional criteria demonstrate the extent to which CCG policy can restrict access to treatment beyond NICE guidance.

7. Smoking status

There is a clear discrepancy between NICE guidance and CCG policy when discussing smoking, demonstrating a further barrier to individuals/couples seeking fertility treatment.

NICE guidance simply states that the individual/couple should be warned of the risks of smoking to fertility treatment outcomes and referred to smoking cessation programmes. 11 CCGs follow this guidance and place a focus on lifestyle recommendations.

However, *116 CCGs (86%) take the guidance a step further, denying treatment if either partner smokes*. The justifications for these decisions tend to focus on the impact of smoking on the success of fertility treatments, as well as the welfare of the child who may be harmed by passive smoking.

Some CCGs tighten this criteria further, by stipulating a minimum amount of time that couples must have quit smoking before referral to fertility services. *51 CCGs (38%) place a minimum time period for both partners*. Like BMI criteria, the minimum time period for how long couples must have quit smoking presents a further barrier for fertility treatment access. The variation in this time limit, ranging from 28 days to 12 months, demonstrates the diversity in experience for individuals/couples living in different parts of the country.

8. Childlessness

The NICE clinical guideline does not make any recommendation regarding existing children, except to mention that CCG policy may vary based on this factor. However, in relation to women aged 40-42, NICE specifically states in its Quality Standard that “the existence of living children should not be a factor that precludes the provision of fertility treatment” (NICE, 2014c).

However, *"childlessness" is a criteria expressed in 129 CCGs' policies (96%)*. Unanimously, these policies state that IVF services will not be available to those who already have children, including children that have been legally adopted. It must be noted that some policies do make an exception for foster children.

Regarding children from a previous relationship, the definition of "childlessness" varies across CCG policies. *88 CCGs (65%) state that a couple is ineligible for IVF if one person has a child from a previous relationship*, and a further 3 CCGs make a judgement on this based on the pre-existing child's age, or where the child lives. Only 17 CCGs (13%) explicitly say that a couple is eligible if one partner has a pre-existing child.

Conclusion

IVF provision is subject to enormous variation across England according to decisions made at the CCG level. Despite an assessment from NICE that IVF provision is cost effective, only 23 CCGs offer the full three cycles that NICE recommends. Services are further restricted in the definition of those cycles, with only 41% of CCGs providing unlimited embryo transfers to support the use of all suitable embryos in a cycle.

The imposition of additional eligibility criteria in certain areas of the country presents a significant barrier to patients, who may be denied IVF based on their age, relationship status, or the fact their partner has a child from a previous relationship. Female age cut-offs as low as 35 are likely to exclude a significant proportion of women who may need access to fertility services, while clinically unnecessary and value-laden clauses about stable, long-term relationships serve to exclude single women who may be desperate to become parents.

The process of establishing infertility is often unnecessarily protracted: 16 CCGs require a minimum of three years of unprotected sexual intercourse before a referral will be made for IVF. The verification of infertility can be particularly onerous for same-sex couples, single women, and others who cannot conceive via vaginal sexual intercourse, who in the majority of cases must self-fund several cycles of expensive (and less effective) artificial insemination before their access to IVF services is granted.

The scale of the divergence between CCG policies and the resulting IVF "postcode lottery" should be understood as the consequence of a systemic problem with the way fertility services are funded in England. The imposition of restrictions is so widespread that no one CCG or group of CCGs can or should be blamed. In the context of intense funding pressures, CCG policymakers have the difficult job of allocating resources to address competing health needs, of which infertility is one. Difficult decisions must be made, but it cannot be right that patients in Bassetlaw are entitled to three cycles of IVF, while those in Brentwood can access none.

The withholding of fertility services has real consequences, both for patients and the health service. Infertility is recognised as a medical condition by the World Health Organisation, and it

is known to cause psychological harm for many of the people affected (WHO, 2016; Kmietowicz, 2012). Many patients who are unable to access fertility care on the NHS are known to travel abroad for care. This is associated with higher multiple birth rates, which are the single biggest risk of IVF to both mothers and babies and sadly associated with higher rates of neonatal death (ONS, 2012; HFEA, n.d.; NICE, 2014d). In addition to the tragedy of this at a personal level, it is relevant to cost effectiveness assessments, since poor outcomes linked to multiple births are costly for the NHS to address later.

Other patients seek IVF care from private providers (private clinics and some NHS hospitals) in England, and the proportion of fertility patients self-funding their treatment is rising across many English regions (HFEA, 2020). This trend towards private provision is likely to be a direct consequence of the difficulty accessing fertility care within the NHS. Private IVF services are however very expensive, costing thousands of pounds per cycle, and for many struggling with infertility this financial burden is simply too great. Fertility services are thus increasingly only accessible to those who can afford to pay.

This status quo is antithetical to the most fundamental principle of the NHS, that care should be provided according to each patient's clinical need and not their ability to pay. This mantra is enshrined in the NHS constitution (NHS, 2015), but it is sadly not manifested in the provision of fertility services. To redress the imbalance between regions, national guidance is needed to guide provision and promote standardisation, to ensure CCG policies are much more closely aligned. Only then will people be able to access the care they need, no matter where they live.

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