

Bristol, North Somerset and South Gloucestershire Clinical Commissioning Group Governing Body Meeting In-Common

Date: Tuesday 7th November 2017

Time: 13.30

Location: Cleve Rugby Club, The Hayfields, Mangotsfield, BS16 9EN

Agenda item: 8.2

Analysis of Fertility Proposals Engagement Exercises

Report Authors: Niall Mitchell, Head of Individual Funding
Louise Fowler, Patient and Public Involvement Programme Lead

Report Sponsor: David Jarrett, Area Director, South Glos

1. Purpose

To note the analysis of the public engagement responses

Recognise how BNSSG benchmark with other CCGs commissioning of assisted conception services nationally

Consider proposal to amend commissioner access criteria of fertility services for BNSSG patients

2. Recommendations

1. Not to proceed with narrowing of the age range for prospective mothers to access treatment to between the age of 30 and 35
2. To implement the following issues considered as part of the consultation:
 - Only fund fertility treatment for couples where neither has a living child
 - Reduce the age limit for prospective fathers and same sex partners to 52
3. To agree to review overall approach to fertility commissioning as part of the operational planning process for 2018/19.

3. Background

Currently, the CCGs will fund one full cycle of IVF/ICSI for patients meeting the criteria within the policy up to the age of 18 weeks before the prospective mothers 40th birthday (taking into account RTT rules) and up to 54 for prospective fathers and same sex female partners. In addition, fertility treatment is funded where one member of the couple does not have any living children.

The Planned Care Control centre [PCCC] with the Individual Funding Request (IFR) team made proposals to further restrict access. The first stage of which was to run a public engagement exercise. The engagement asked for comments on the following questions which formed part of the proposal to amend the fertility policy:

Question 1 : Do you agree or disagree with our proposal to make fertility treatment available to women aged 30-35 years instead of up to 40?

Question 2 : Do you agree or disagree with our proposal to make NHS funded fertility treatment available to people with no children, not people with children from other partners?

Question 3 : Do you agree or disagree with our proposal to no longer offer fertility assessment and treatment for couples where prospective fathers, or female partners in same sex relationships, are older than 52 years of age?

4. Financial/resource implications

The financial impact of policies developed to support the IFR process is assessed during each policy development and supports the CCG in meeting their QIPP targets.

In 2016/17, BNSSG were charged circa £1.8m for assisted conception services, mainly by NBT/Bristol Centre for Reproductive Medicine.

The financial impact of not funding patients with a living child from a different relationship would be a saving of £90 to £180k based on 2016/17 activity charges and a 5-10% secondary infertility rate.

The impact of reducing the upper age range for males and same sex partners is likely to be limited with less than 1% of couples accessing this treatment falling into this age range, therefore the financial saving will be up to £18k.

5. Legal implications

The engagement exercise has challenged that the proposed age limits were unlawful and discriminatory. The NHS is only able to restrict treatments on the basis of age where there is a clinical reason to do so and this paper sets out the clinical justification for restricting further the age limits for fertility treatment.

6. Risks/mitigations

The PCCC have considered the policy review and public engagement responses and consider that the risk of legal challenge is high given the inequality in respect of age which will be exacerbated by this proposal.

Due to the nature of the IFR process, it is open to both administrative and judicial challenge by patients and clinicians unhappy with decision made as part of the panel process. The IFR team has implemented a significantly robust decision making process to minimise the possibility of a successful challenge including ensuring that patients are fully informed of the decision making process and the reasons for a decision.

The options to amend the policy as set out in this paper has previously been assessed by the CPRG which has members from appropriate clinical services at each of the Acute Trusts as well as Public Health and primary care GPs.

7. Implications for health inequalities

The current and proposed revised policies do not offer any Fertility Assessment and / or treatment to Male Patients within a same sex relationship. This decision has been taken due to the complex legal issues associated with surrogacy arrangements required to enable a same sex male couple to have a child.

The legal complexities surrounding surrogacy also mean that patients who are going through or have gone through Gender Reassignment are also not eligible to access any Fertility Assessments/ Cryopreservation's of Sperm / Gametes and Treatment.

This also extends to female patients who have an absence of womb through congenital and non-congenital reasons.

Applications can be submitted through the IFR Panel route for consideration on a case by case basis, where exceptionality to this known cohort can be demonstrated.

8. Implications for equalities (Black and Other Minority Ethnic/Disability/Age Issues)

The IFR process and associated policies mean that some patients will not qualify for some treatments. Equality Impact Assessments (EIA) and Quality Impact Assessments (QIA) have been completed and will be updated in line with any Governing Bodies decisions. These documents are live and as such will be regularly updated.

9. Consultation and Communication including Public Involvement

This paper presents the outcome of a public engagement exercise between 15th July and 15th September 2017

10. Appendices

Appendix A - IFR Fertility Online Engagement Exercise - Quantitative and Qualitative Analysis

Glossary of terms and abbreviations

CPRG	Clinical Policy Review Group - quarterly meeting coordinated by IFR team in order to clinically review / update existing policies against new NICE guidelines and other developments. CPRG also clinically evaluates new policies identified.
Individual Funding Request	Where a CCG has published a policy stating that certain treatments are not routinely funded. Treatment will only be funded via agreement from commissioners in exceptional circumstances
Criteria Based Access [CBA]	Where a CCG has published a policy setting out eligibility criteria. If clinicians are content that the patient meets the criteria, they may proceed to treat without seeking funding approval.
Prior Approval [PA]	Where a CCG has published a policy setting out eligibility criteria. Clinicians, where they feel patients meet the criteria, must seek funding approval from the commissioners prior to treating.
Planned Care Control Centre [PCCC]	Turnaround program group.

Appendix A

IFR Fertility Online Engagement Exercise

Quantitative and Qualitative Analysis

27 September 2017

Version Control

Draft 1	Karen Michael-Cox	27 Sept 2017
Draft 2	Louise Fowler	27 Sept 2017

Clinical Chairs:

Dr Martin Jones (Bristol CCG)

Dr Mary Backhouse (North Somerset CCG)

Dr Jonathan Hayes (South Gloucestershire CCG)

Chief Executive: Julia Ross

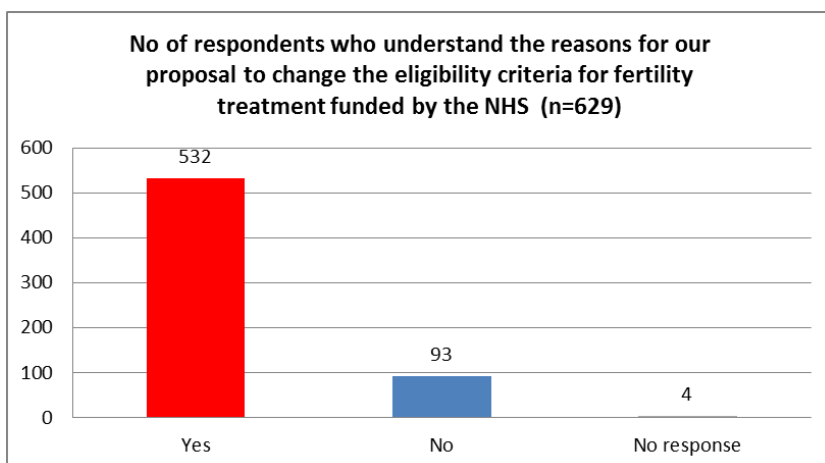
KEY MESSAGES

- 629 online responses to fertility engagement exercise
- 76% of respondents live in BNSSG
- 74% of respondents are aged between 25 and 44. 88% of respondents in these age categories are female.
- 85% of respondents are white.
- 75% of respondents are female and white.
- 91% of respondents are heterosexual

All responses break down as:

Bristol	521
North Somerset	63
South Gloucestershire	45

Chart 1



85% (532) of respondents said they understood the reasons for our proposal to change the eligibility criteria for fertility treatment.

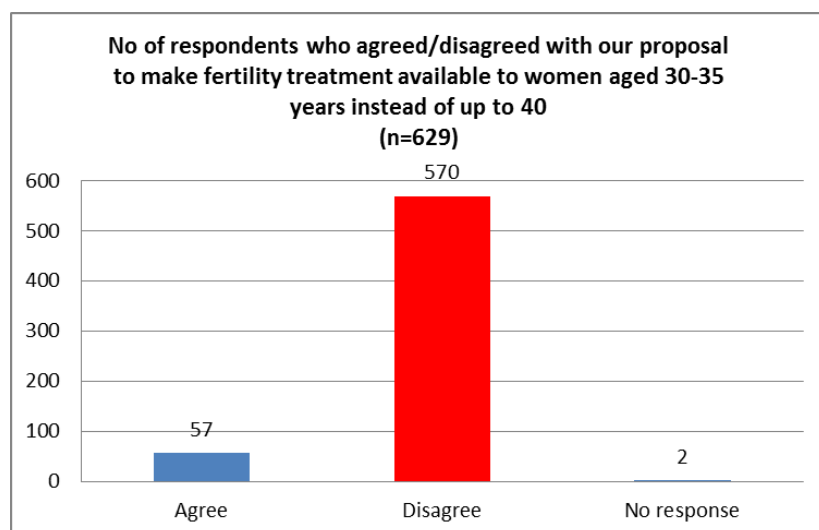
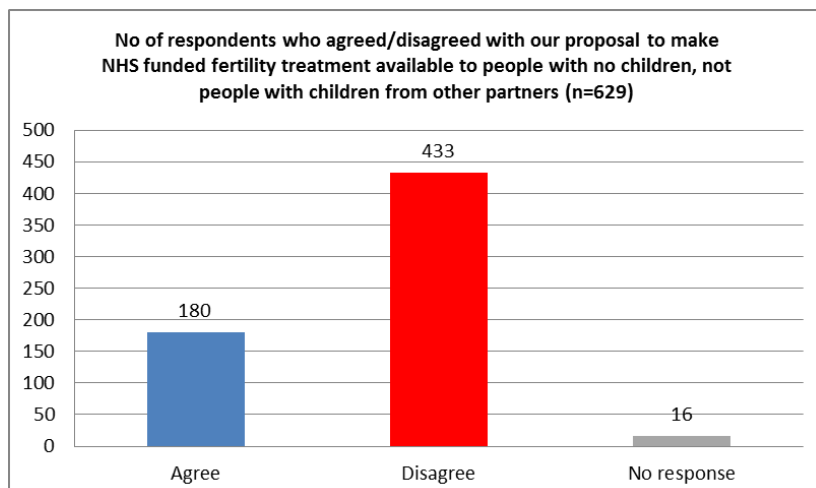


Chart 2

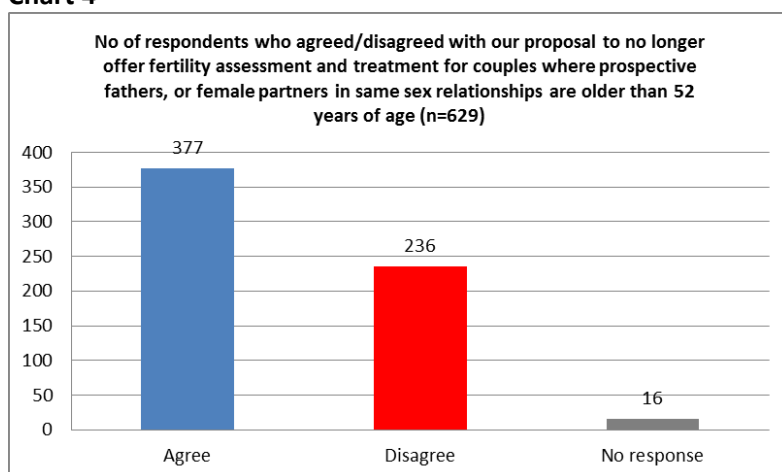
90% of respondents (570) disagreed with our proposals to change the age limit for women.

Chart 3



69% (433) respondents disagreed with our proposal to people with no children, excluding couples where one partner had children from a previous relationship/s.

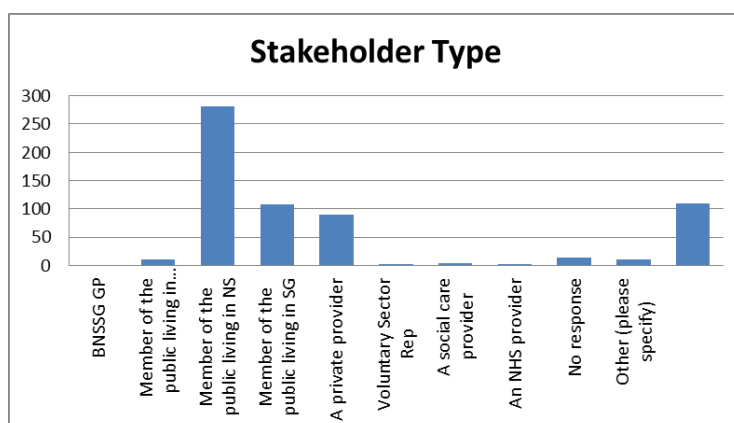
Chart 4



60% (377) of respondents agreed with our proposals to no longer offer fertility assessments and treatments for couples where the prospective partners are older than 52 years.

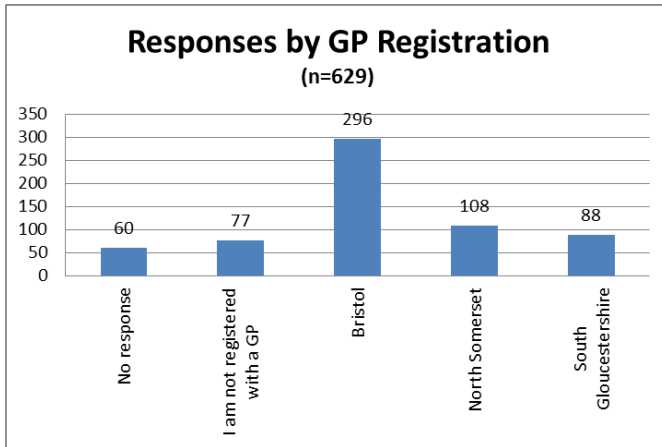
Chart 5

BNSSG GP	10	2%
Member of the public living in Bristol	282	45%
Member of the public living in NS	108	17%
Member of the public living in SG	89	14%
A private provider	1	0%
Voluntary Sector Rep	4	1%
A social care provider	2	0%
An NHS provider	13	2%
No response	11	2%
Other (please specify)	109	17%



The majority of respondents were members of the public living in BNSSG (76%). There were 10 responses from GPs in BNSSG, and 13 responses from other NHS providers.

Chart 6



78% of respondents are registered with a BNSSG GP. The majority of respondents were registered with a Bristol GP.

Bristol	296
North Somerset	108
South Gloucestershire	88

Chart 7

74% of respondents are aged between 25 and 44.

413 (88%) of the total 468 respondents in these age categories are female.

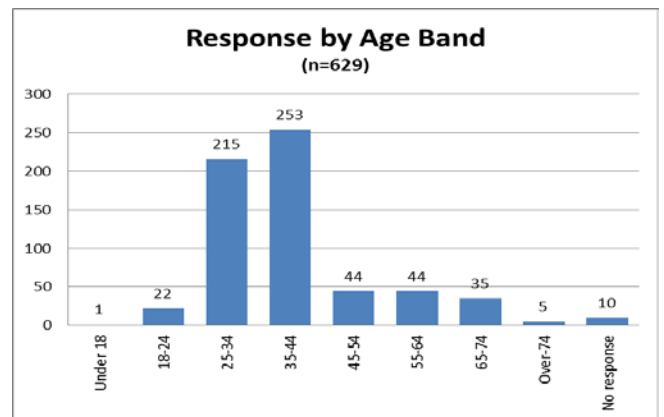
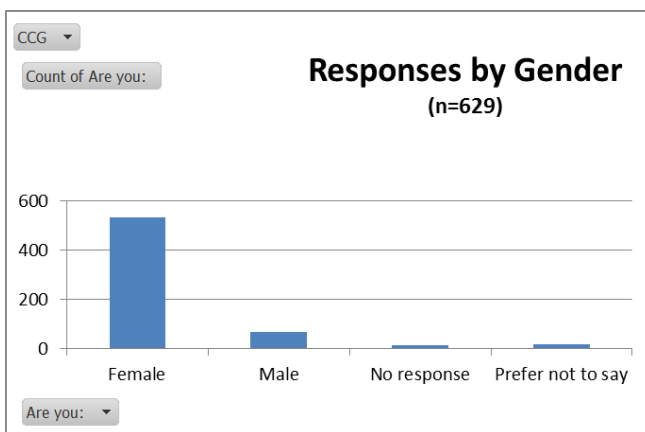


Chart 8



84% (532) respondents are female.
11% of respondents are male.

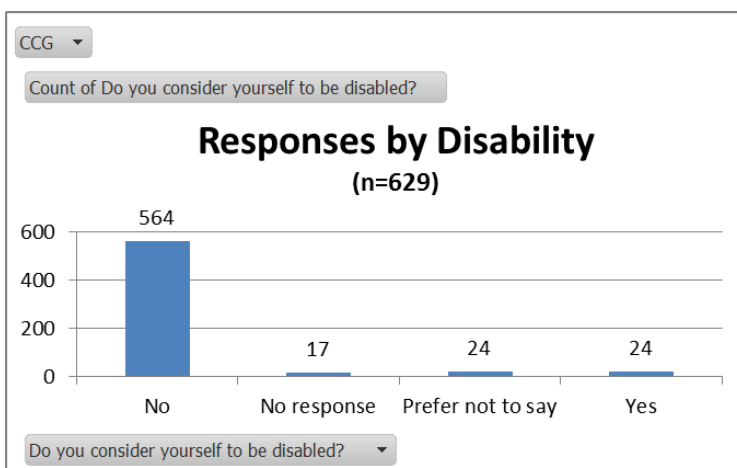
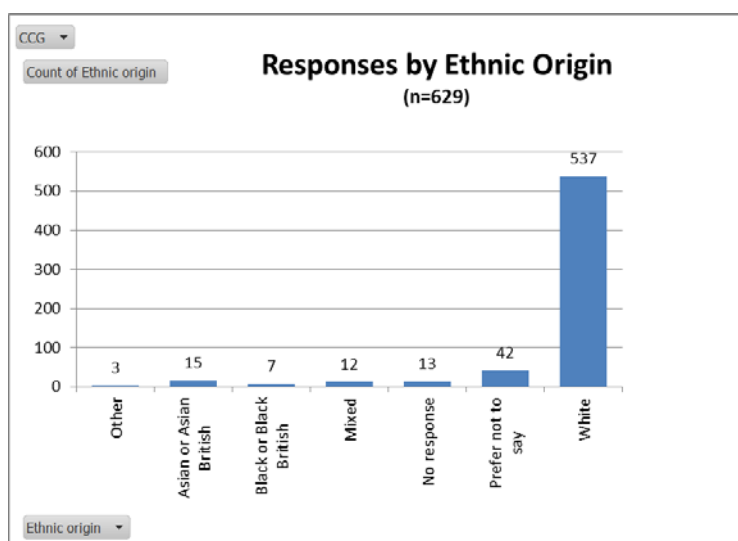


Chart 9

24 patients identified as disabled = 4%

Chart 10



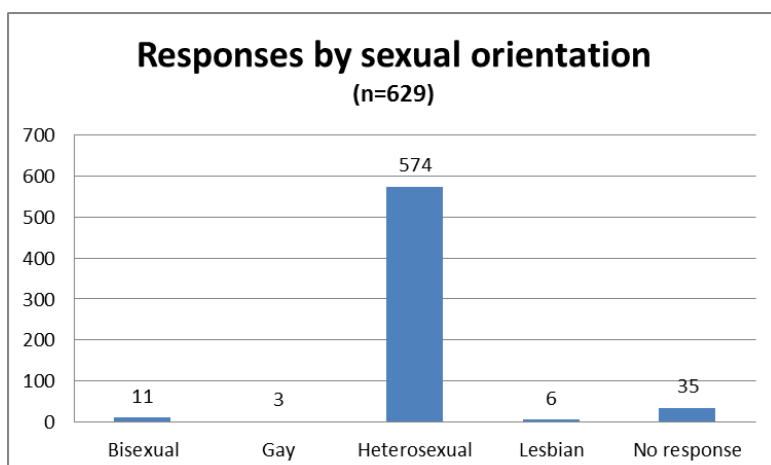
85% of respondents are white. There are low numbers of responses in other ethnic groups.

75% (476) of respondents are female and white.

Correlation between white responses and Bristol population match

6% BME responses but could be higher due to the prefer not to say and no response

Chart 11



91% of respondents identified themselves as heterosexual. There were low numbers of responses from bisexual, lesbian and gay people.

3% of sample identified themselves and lesbian, gay or bisexual.

This proposal generated a significant response from the local community who completed the survey in large numbers. The survey received 629 responses and people who completed it had taken time to respond in significant depth, providing considered and thoughtful responses which considered each of the elements of the proposal on their own merits.

We place great value on the feedback we receive from our local residents and each of these responses has been read carefully and we have then analysed the themes which people have raised. Many people identified multiple themes in their answers.

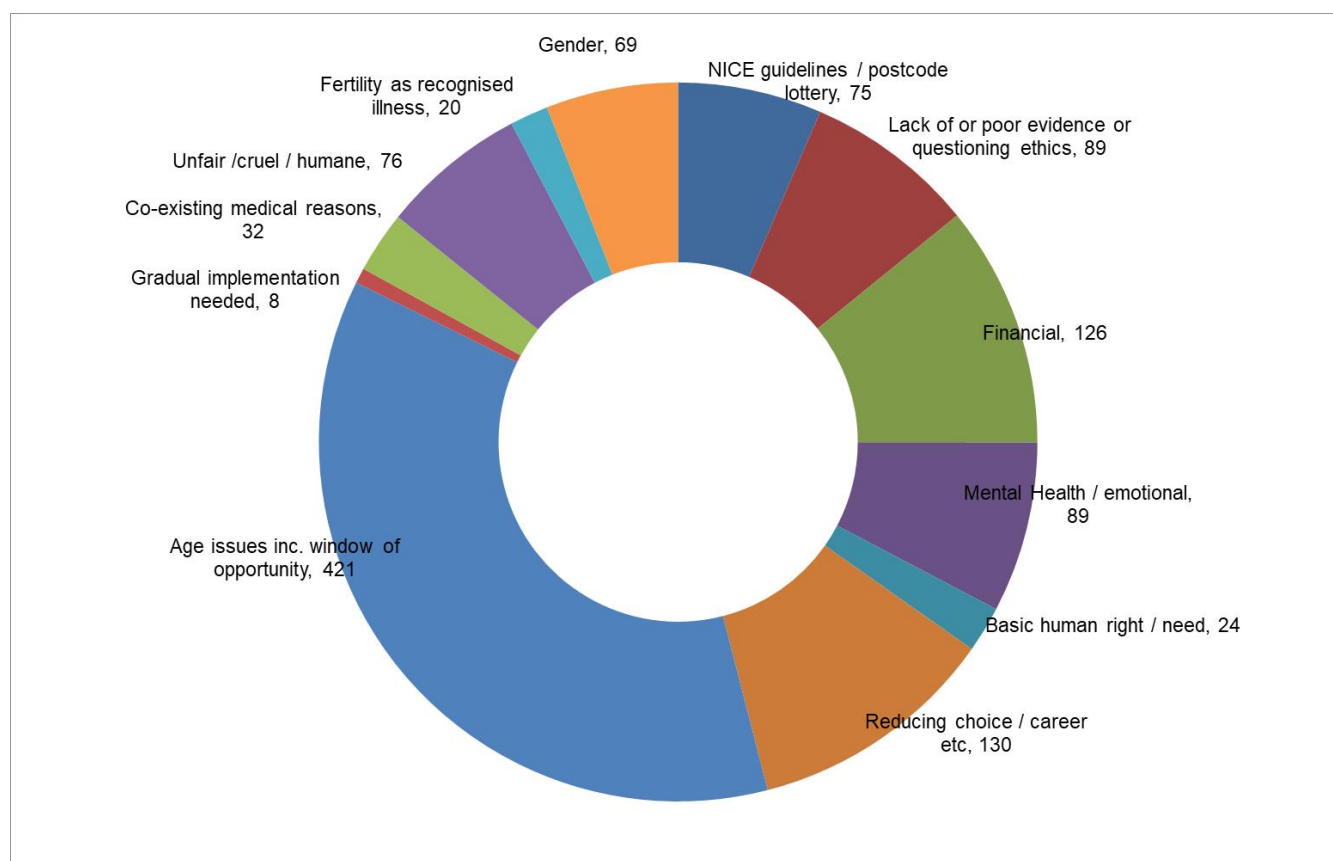
Responses are set out below under each of the three questions which were posed, and it should be noted that someone who disagreed to one element of the proposal did not necessarily object to all elements.

Question 1 : Do you agree or disagree with our proposal to make fertility treatment available to women aged 30-35 years instead of up to 40?

Out of 629 responses to this survey, 90% (563 people) did not agree with this proposal.

We identified twelve key themes raised by people who disagreed with this proposal. Figure 1 below provides an illustration of the key themes identified by these respondents and the numbers of people who highlighted that particular theme.

Figure 1



Given the nature of the proposal, it is unsurprising that the theme cited by the highest number of people (421) was that of age. Of these many believe that the proposal is discriminatory on the basis of age. A lot of people pointed to the narrow window of opportunity and the time taken to move through the referral process. They highlighted that a five year window would need to allow for time to secure a referral from a GP, appointments at clinics, tests and procedures, and assisted conception approaches (such as medication to stimulate hormone production), before a couple even reached a move to IVF or ICSI. One woman noted that she had become pregnant with her first cycle of IVF aged 35, but that it had taken her “over 4 years to get this far”. Many questioned the difficulty of achieving all this within a five year window, even if timing was optimum, that is to say a

couple starting to try when the woman was aged 28, and then being referred to the service at age 30.

Some people pointed out the complexity of factors which contribute to infertility, arguing that age was only one of these, and in some cases not a key driver.

A strong objection focused on the trend for people to start families later in life, and argued that it was unfair to push women towards a position where in order to hit this five year window they had to have settled down and started trying for a family by the age of 28. For many respondents this was not a possibility as they pointed out they were not in a relationship by this age, or that they were not sufficiently financially stable to have children, or were pursuing careers. One person noted that “The average age of women marrying men in England and Wales is now 34.6 (ONS, 2014 data released Mar 2017) and on an upwards trajectory”.¹

The five year window also meant that those outside of it would have to pay privately and many people pointed out that “Many people can't afford private treatment, so only those with the ability to pay huge sums will be eligible for ivf”.

Many people noted that they felt they “done the responsible thing” by waiting to ensure they were financially secure, able to afford a home and provide for a child, and/or in a stable relationship before trying for a baby, and that the proposal went against this.

Conversely there were strong objections from many to the lower age limit being raised from 28 to 30. Respondents described discovering that they had infertility issues in their twenties, and argued it would be unfair to have to wait for 8 to 10 years under this proposal, whilst their fertility levels were falling, before they could seek help.

Some people suggested an alternative age window, with 33 to 38 or 32 to 40 being mentioned, but for many the issue was simply that placing a narrow age window was problematic in itself.

Many people highlighted that the need to go through fertility treatment is a challenging time for couples emotionally, and this was often reflected in the use of language and the sentiments outlined. Many spoke of unfairness and some felt the CCG was being “cruel” or “inhumane”. The urge to have a child was described frequently as a basic right, or biological urge, and many respondents argued that those who have not been through the experience could not understand the depth of distress it causes. A strong emerging theme was around mental health and emotional wellbeing, as respondents described the psychological toll which infertility could take and their fears that if this proposal was implemented it could cause mental and emotional harm. Some also pointed out that this in itself could carry a financial burden for the CCG. One person wrote that “This is a very short-sighted proposal which may reduce costs of fertility treatment but will significantly increase levels of depression and mental illness”.

A significant number of people questioned the evidence presented to support this proposal. One person stated that: “The statistics used above explain the difference in natural conception rates

1

<https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/marriagecohabitationandcivilpartnerships/bulletins/marriagesinenglandandwalesprovisional/2014#at-what-age-are-couples-getting-married> accessed 19th September 2017

between age 35 and 38. This does not explain why someone age 36/37 would therefore not have a successful IVF attempt. Natural conception is no relation to IVF success rates due to the reasons people need IVF being very different.”

The proposal was perceived by many to be particularly unfair because BNSSG already restricts IVF/ICSI to only one cycle, compared to NICE guidelines to provide three cycles. The proposal to restrict again by age was therefore as placing additional barriers in place within a service that was already seen as limited. A common theme was the notion of a ‘postcode lottery’ and one person noted that “we pay the same taxes as everyone else in the country so should be entitled to same treatment”.

Gender was drawn out as a key theme, and many saw it as ‘discriminatory against women’ or that it “disproportionately affects women” with one person pointing out that “Men are able to have IVF treatment up to 50+ years, it seems like discrimination to reduce the age women can access IVF treatment”. Some respondents spoke of a feeling that this proposal was ‘punishing’ or ‘penalising’ women who may have chosen to pursue careers, or to wait for financial stability, or indeed simply not been ready to have children at an earlier age. One respondent noted the key timescale of early thirties as a time when women would need to develop their career. Some women questioned the underlying assumption implicit in the proposal that infertility was a female issue, pointing out that if the issue lay with the male partner under this proposal, the woman still had to be between 30 and 35. As one person noted, a woman might “be 36 and fertile but with a partner who had problems that could be treated very successfully”. Some felt that there was particular discrimination for women over 35 who would not be able to afford to pay for their own treatment.

A significant number of people pointed out that infertility is a medical condition recognised by the World Health Organisation. Tied to this was often a debate around how the NHS should prioritise funding, and whether it was fair to ration treatment for infertility, whilst treating other conditions which some felt were in some way “self-imposed”.

Several people argued that this would cause health inequalities.

Of those who supported the policy change, the majority (19) cited that they agreed with the notion and or evidence that there was a higher probability of success for IVF and sixteen people said that the NHS has to prioritise where it spends its money. Furthermore, six people said that the NHS shouldn’t fund fertility treatments at all and expressed their views very strongly: *‘I don't believe that the NHS should be paying for any fertility treatments. I don't have or want children and don't see why others should have them at my, the taxpayers, expense.....’* There were some who said that having children is not a right and others felt that adoption is an option. Others felt that having children later in life was detrimental to health of both the mother and in one respondent, citing her own experiences of having older parents.

Do you agree or disagree with our proposal to make NHS funded fertility treatment available to people with no children, not people with children from other partners?

We identified eleven key themes raised by people who disagreed with this proposal, with a further category which we've termed as 'other', made up of a variety of individual comments illustrated in Figure 2.

Out of the respondents for this question, 430 people disagreed with the proposal and 177 agreed with 15 people leaving it blank.

The main theme arising from the respondents who disagreed was the notion that societal norms are such that complexity in family life is common with high divorce rates, blended families and cultures. Several respondents cited that they don't see or bring up partners' children, and have nothing to do with the life that they lead now, and they could be part of previous and estranged relationships with the child(ren) living abroad. This point is illustrated most keenly by a respondent saying *'My partner had a holiday fling with a girl nine years ago. He has since found out that it resulted in a child. He is supporting financially but they do not have a relationship. I have never met his daughter. It's incredibly unfair that this would prevent us from starting a family.'*

Another illustrated several themes that came out strongly, that step children are not the same as people's own biological children *'By doing this you assume that people treat children as commodities; "I can share the child that my partner has had with a previous partner, therefore I have a child and I do not need another"'*.

Another theme that came out strongly was the notion that this policy is penalising or punishing, being cruel or unfair; *'This is wholly unfair. My partner already had a child from a previous relationship. Why should I be punished for this?'*

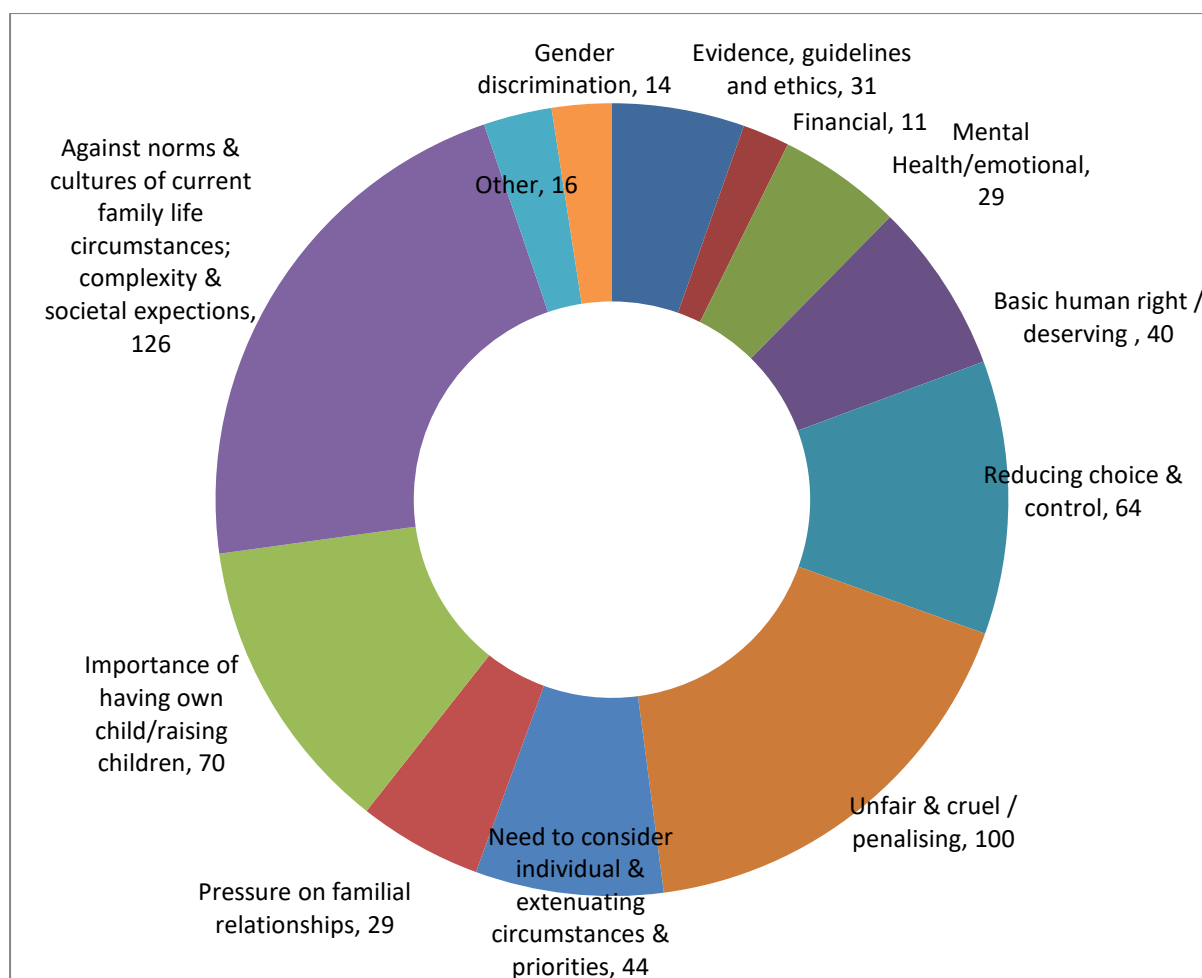
People felt that this aspect of the policy too was discriminatory as it would predominately affect women but the reasons were different to the first question; *'If I met a man with previous children it shouldn't exclude me from parenthood - it is discriminatory.'*

Many people discussed the notion that infertility shouldn't be predicated on the couple; that it affects people individually *'The person that hasn't had a child previously is still childless.'* This notion was often combined with the individual's right to treatment' and that partners' decision/circumstances to have children prior should not impact their partners' right to treatment. *'Fertility treatment is the only aspect of healthcare in which you are not treated as an individual, but as a couple, and so there are double standards to be met to qualify for treatment.'*

The CCGs are accused of dictating who is 'worthy' of treatment, applying value judgements and is asked to justify how it balances spend on peoples' lifestyle choices such as smoking, drinking, obesity against illnesses such as infertility; *'it's as though the NHS judges me for this.'*

There was recognition that this policy could lead to undue pressure on relationships with the partners or build-up of resentment of the child outside of that relationship *'Your partner having a child should not deny you from becoming a biological parent. This is very cruel and can build resentment towards the child and plant a seed for difficulties in a relationship.'*

Figure 2: Themes arising from those who disagreed with the proposal.

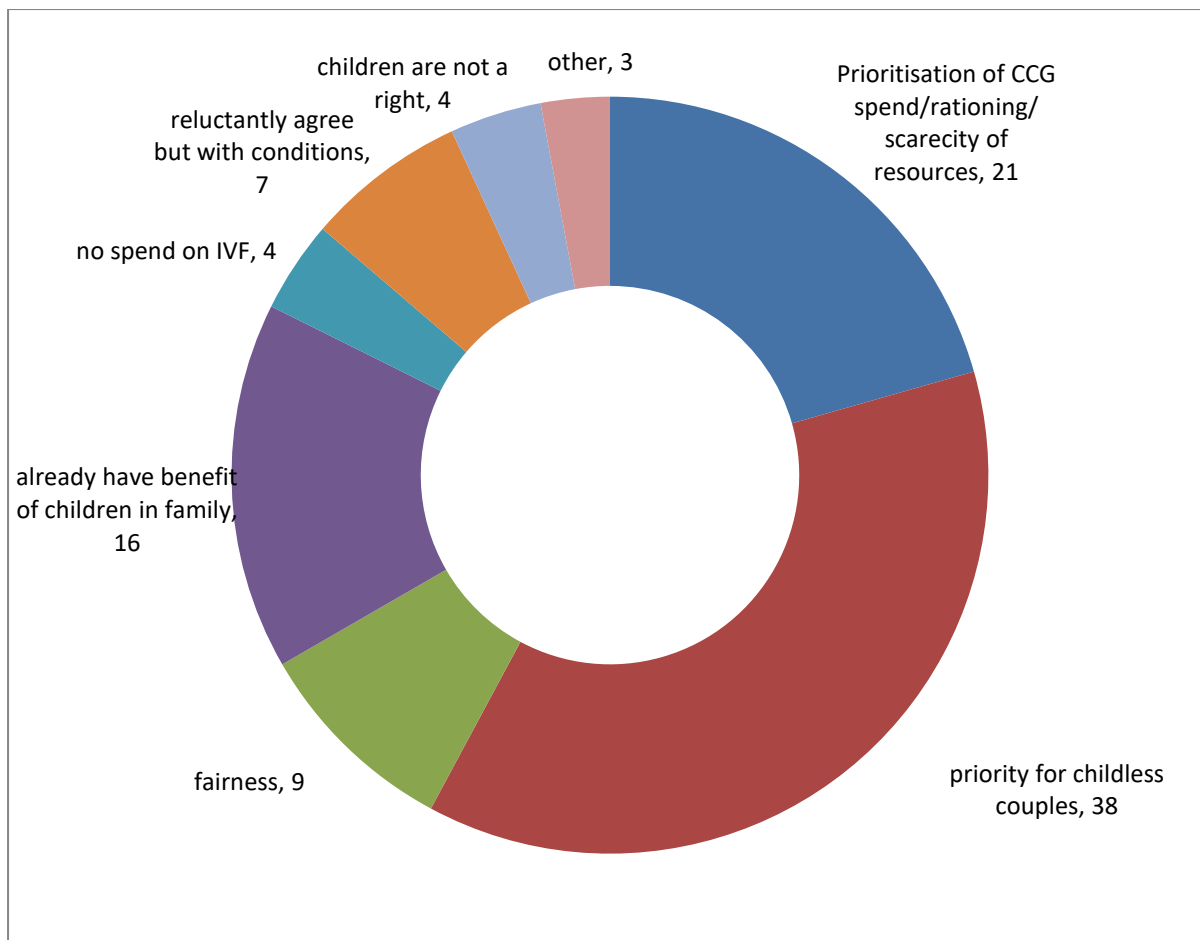


For the 177 that agreed, there were fewer actual comments, however it was noted by the majority that they thought that priority should be given to couples who were childless and often they noted this in conjunction with comments that if resources were tight, then this is where they would like the focus to be. Some went further and agreed, but they highlighted certain ‘conditions’; *‘I agree but this issue is simply not black and white....’* And another said *‘If we need to make cuts although many people may not agree with this point I feel that it is better than the age restrictions.’*

Many people recognised that resources are scarce and that the CCG needs to prioritise with a couple using the word ‘rationing’. Being ‘fair’ was a sentiment that was often phrased.

A few people highlighted that people already have children in the family and that the aim of IVF was to benefit those people who are childless. A few people came up with stronger sentiments, expressing that children were *‘not a right’* and that there should be no spend of IVF services at all.

Figure 3: Themes arising from those who agreed with the proposal



Do you agree or disagree with our proposal to no longer offer fertility assessment and treatment for couples where prospective fathers, or female partners in same sex relationships, are older than 52 years of age?

This question was answered by 607 people, of whom 61% agreed with this element of the proposal, whilst 39% did not.

Of those who agreed with this part of the proposal, the most common reason cited was that this felt reasonable, or that they accepted that if there must be cuts, this was a sensible cut-off point, or one which would have a minimal impact. The second most common reason for people to agree was that they felt that people over the age of 52 would be too old to be parents, with many pointing out that this could lead to a parent being over 70 when the child was a teenager.

Amongst the 235 people who disagreed with this part of the proposal the strongest theme which emerged were a belief that this was discrimination on the basis of age, or that age was not a relevant factor, and this was strongly linked to the second most common emerging theme which was that people felt that there had been insufficient evidence presented to justify this proposal. Some people felt this was particularly the case for same sex couples where they pointed out that the fertility and age of an older female partner was entirely irrelevant for conception. Some people felt that the proposal was particularly unfair on same sex couples, although there were others who felt that same sex female couples were in fact receiving preferential treatment as in a heterosexual relationship the woman had to be under 35. A common suggestion was that eligibility should be based on the age of the female partner who would potentially be carrying the child, whilst others argued strongly for decisions to be made on a case by case basis. However, two people disagreed with this proposal on the basis that they felt the proposed limit of 52 was not *low enough*.

Five people spoke of the 'right' to have a child whilst others emphasised the importance of personal choice and individual lifestyles. Several people felt that the CCG was imposing a value judgement by deciding who could have children and who could not.

Where the theme of finance emerged this was mainly centred on the idea that the proposal was solely a cost-cutting exercise. One person felt that there was an imbalance in decision making around budgets, questioning why other budget decisions were not made on the basis of age, or on a perceived decision to prioritise other services over this.

Appendix B – Statistical Evidence On Fertility Success Rates

Average Age of having First Child

The Office of National Statistics reported in their statistical bulletin: [Births by parents' characteristics in England and Wales: 2015](#) reported the following relevant data:

- The average age of first-time mothers was 28.6 years in 2015, compared with 28.5 years in 2014.
- 75.1% of live births in 2015 were to mothers aged under 35 years.
- A small rise was also recorded among the average age of mothers, up to 30.3 years in 2015 from 30.2 years in 2014.
- The report does recognise that parents are leaving it longer before having children *“The average age of mums and dads in England and Wales has increased by almost 4 years over the last 4 decades. At the birth of a child in 2015, fathers averaged 33.2 years of age and mothers 30.3 years. Falling birth rates among the under-30s and rising birth rates at older ages reflect trends evident since the mid-1970s to delay childbearing to later ages.”* Nicola Haines, Vital Statistics Outputs Branch, Office for National Statistics.

Summary: Whilst the statistical evidence does support the view that parents are leaving it later to have children, the average age of first time mothers is 6.4 years below the proposed 35 age limit.

Conception and Live Births by Age Fertility Treatment

The Human Fertilisation and Embryology Authority [HFEA] which is responsible for regulating fertility treatment report each year on [Fertility treatment 2014 - Trends and Figures](#) and this report included the following relevant data and comments:

- “The likelihood of getting pregnant following IVF treatment is strongly linked to the age of the woman being treated. On average, a woman aged 18-34 is markedly more likely to conceive than a woman who is older.”
- Fertility treatment for patients 35-37 was 5% less successful than patients 18-34.

Table 8: Pregnancy rate (per embryo transfer) for patients receiving IVF treatment using their own fresh eggs, 2013 and 2014

Age	2013	2014
18-34	41.7%	43.7%
35-37	38.3%	38.7%
38-39	30.2%	30.3%
40-42	23.0%	21.3%
43-44	12.3%	11.3%
45+	7.0%	2.2%
All ages	35.5%	36.3%

- The live birth rate per cycle started using the patient’s own fresh eggs also falls from 32.8% for patients 18-34 to 29.5% for patients 35-37 in 2013, although this has narrowed from 2012.

Table 12: Live birth rate, per cycle started, fresh own eggs, 2012 and 2013

Age	2012	2013
18-34	32.9%	32.8%
35-37	27.3%	29.5%
38-39	20.7%	21.8%
40-42	13.2%	13.7%
43-44	5.4%	4.9%
45+	1.1%	2.0%
All ages	25.9%	26.5%

- Prior to treatment with IVF/ICI, patients are required under the current and proposed fertility policies to first try assisted conception treatments where appropriate. The HFEA rates also show a fall in birth rates for patients 35 and over receiving this treatment.

Table 20: Live birth rate per DI cycle started, 2013

Age	Stimulated	Unstimulated
18-34	21.6%	13.9%
35-37	12.0%	12.8%
38-39	8.8%	8.4%
40+	4.8%	3.0%
All ages	14.6%	11.2%

Summary: The HFEA data does report and recognise the impact of age on successful conception and birth rates using fertility treatments.

Note: The 2014 HFEA report is the latest available due to the time taken for patients to complete the pathway, give birth etc.

Locally Reported Data

At the outset of this process in 2016, during discussions with BCRM clinical leads, we asked them to report their success rates and they provided the following data in comparison to the national picture showing nearly 10% lower success rate in patients 35 and over:

Age	Success Rates Nationally	Success Rates BCRM	Cycles undertaken
Under 35	43.7%	47.3%	172
Aged 35-37	38.7%	37.4%	122
Aged 38-39	30.3%	45.9%	46

BCRM – “Please exercise caution when interpreting this data where the number of cases <50 as this may cause a statistical anomaly”

In addition, their website contains the following table on success rates:

2014 (Jan-June) IVF/ICSI Data, Live Birth Rates per cycle started by age						
	Below 35 yrs	35-37 yrs	38-39 yrs	40-42 yrs	43-44 yrs	Over 44 yrs

Live birth rate per cycle started	36.8% (161/486)	20.3% (66/325)	12.6% (30/277)	15.2% (5/33)	5.8% (5/33)	
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Summary: Local data mirrors national data generally in reporting reduced success rates in patients over the age of 35.

Lower Age Limit - Peak Fertility Age

There is no absolute clinical agreement on when female fertility peaks although this is generally accepted to be in the mid to late 20s. A study in 2004 of 782 European couples reported that the percentage of infertility was estimated at 8% for women aged 19-26 years, 13-14% for women aged 27-34 years and 18% for women aged 35-39 years. {*Increased infertility with age in men and women, Dunson D.B. et al, Obstetrics and Gynecology; Jan 2004; vol. 103 (no. 1); p. 51-56.*}

The proposal of patients essentially starting the fertility pathway at 28 years old was considered in a meeting with the local fertility clinicians. We were advised that the average female will start to reduce fertility success rates from the age of 28 and having had 2 years attempting to conceive unsuccessfully and therefore defined as suffering from sub-fertility, would then be eligible to access the fertility pathway.

Patients with confirmed infertility are able to access fertility treatment from the age of 28 and do not need to attempt to conceive for 2 years.