

REPORT TO:	Health and Social Care Scrutiny Sub Committee 21 March 2017
AGENDA ITEM:	13
SUBJECT:	To review the decision of the CCG to vary the provision of IVF and ICSI Assisted Conception Services
LEAD OFFICER:	Paula Swann, Chief Officer Croydon CCG
CABINET MEMBER:	N/A
PERSON LEADING AT SCRUTINY COMMITTEE MEETING:	Paula Swann, Chief Officer, Croydon CCG Stephen Warren – Director of Commissioning

ORIGIN OF ITEM:	This item has been offered to the committee by CCG officers to share the decision to vary the provision of IVF and ICSI Assisted Conception Services.
BRIEF FOR THE COMMITTEE:	<p>Croydon CCG has a substantial financial challenge. We must live within our resources and focus them on the greatest health needs of our population to secure the best possible health outcomes for our local people. This means prioritising some services over others.</p> <p>To ensure financial sustainability the CCG is required to deliver £36m (7% of resources) in savings in 2017-18. To that end the CCG has considered its policy on funding and commissioning an element of the specialist assisted conception services, IVF (In Vitro Fertilisation) and ICSI (Intracytoplasmic sperm injection) services.</p> <p>On the 27th September 2016 the CCG advised the Health, Social Care & Housing Committee (OSC) of its approach to achieving financial recovery and set out a number of areas that it proposed to engage and/or consult on. It set out schemes that either offered limited clinical effectiveness and/or poor value for money and proposed that these services were either recommissioned, which could include providing them differently, or in some cases reducing the provision or changing thresholds of these services in Croydon.</p> <p>This included the proposal to reduce the provision of IVF and ICSI and to undertake consultation on this proposal.</p>

On the 16th December 2016 the CCG shared with OSC members for comment i) draft IVF Consultation document and ii) Draft Consultation Plan to OSC with a view to carrying out a consultation process from 4th January to 1 March 2017 in line with the plan.

The Governing Body (GB) at its meeting on the 14th March carefully considered the proposal to stop the routine provision of IVF and ICSI services and the response from the consultation.

- In making the decision the CCG GB reviewed the: rationale
- Public and Patient Consultation Report (Appendix B)
- Prioritisation Matrix (Appendix C)
- Equality Impact Assessment (Appendix D)
- Alternative Provider provision (Appendix E).

It decided to fund IVF and ICSI only for those with exceptional clinical circumstances.

It also agreed that the decision would be implemented from the 14 March (except for applications received by 14 March which meet the approval criteria and approved cases on the waiting list).

The GB also considered whether the CCG should specify any eligibility criteria exceptions or, as recommended, solely utilise the Individual Funding Request (IFR) process. It concluded that it would be difficult to agree any specific criteria and these also reflected views obtained during the public consultation.

The GB also agreed to continue to review the decision on an annual basis in line with other service priorities and the CCG's financial position.

This has been a very difficult decision for the Governing Body as it will result in a small cohort of patients who will not receive NHS treatment and could impact on the parenting ambitions of some Croydon couples. However, it cannot be taken in isolation from consideration of the need to ensure continued provision of other higher priority services such as CAMHs or Urgent Care.

CORPORATE PRIORITY/POLICY CONTEXT:

This decision supports the CCG's Financial Recovery Plan.

FINANCIAL IMPACT

The annual cost of providing the service is £888k. The full year effect of savings are likely to be £829k.

1. RECOMMENDATION to the Committee

To discuss, consider and note the decision of the Croydon CCG Governing Body on the 14th March to vary the provision of IVF and ICSI services in Croydon.

4. CONSULTATION

The CCG consulted from 4 January to 1st March 2017 and the detailed report is attached at Appendix B. A summary is provided in Section 9 of the Report.

5. HUMAN RESOURCES IMPACT

There may be an impact on staff that currently provide IVF/ICSI services in CHS if they cannot be redeployed.

6. EQUALITIES IMPACT

A full equalities impact has been completed and is attached at Appendix D

9. PARTNERSHIP AND COLLABORATIVE WORKING

Croydon CCG is working collaboratively with SW London CCGs around potential areas of decommissioning including IVF services.

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BACKGROUND DOCUMENTS:

None

IVF and ICSI routine funding – The Case for Change

1. Background

Croydon CCG has a substantial financial challenge. We must live within our resources and focus them on the greatest health needs of our population to secure the best possible health outcomes for our local people. This means prioritising some services over others.

To ensure financial sustainability the CCG is required to deliver £18.4m of QIPP savings in 2016/17 as well as £36m in savings in 2017-18. To that end the CCG must consider changing its policy on commissioning specialist assisted conception services which includes decommissioning this service and ceasing routine funding of assisted conception services

On the 4th October 2016 the Governing Body approved a paper setting out the CCG's Financial Savings Plan 2016/17 and 2017/18. This paper included the recommendation to engage with the public on proposals to reduce service provision as part of the CCGs Financial Savings Plans for 16/17 and 17/18. It set out schemes that offered limited clinical effectiveness and/or poor value for money and proposed that these services were either recommissioned, which could include providing them differently, or in some cases reducing the provision or changing thresholds of these services in Croydon. The areas considered included:

- Assisted fertility treatment services (IVF- in vitro fertilisation and ICSI – intra-cytoplasmic sperm injection) – reduction in provision
- Foxley Lane Mental Health Ward to be decommissioned and reprovided in the community
- Reduced provision in a number of Prescribing related areas including gluten-free and emollients, self-care medication, vitamin D for maintenance and specialist baby milks.

Croydon CCG has a strong track record of addressing its financial challenge. The CCG has delivered a continually improved financial position including £49.5m million of QIPP savings (Quality, Innovation, Productivity and Prevention) over the last four years.

Our focus is on transforming services to make them more efficient, effective and sustainable. We have a clinically led service redesign approach which includes:

- Outcomes Based Commissioning (OBC) programme for patients over 65 years old alongside Croydon Council
- New network of urgent care services launching in April 2017
- Real improvements in cancer, mental health and A&E, urgent care and community services

In order to deliver a sustainable financial position the CCG has had to further develop our Improvement and Financial Recovery Plan and make tough decisions, working with the public, patients and partners and stakeholders to consider how the CCG can effectively focus its resources to greatest need to deliver better outcomes. Croydon CCG is facing its biggest financial challenge yet.

The CCG needs to make savings of almost £36 million in the next financial year, which is around 6% of the commissioning budget for local health services of £482.3 million. As a result of these challenges, the CCG identified a number of areas where it could make potential savings that would contribute towards helping the CCG get into financial balance. These areas

of potential savings were then assessed against a set of criteria before being developed further.

Within this requirement we have had to ensure we engage appropriately and proportionately with local people and stakeholders and partners over these decisions and ultimately look at each within the wider context of prioritising the limited resources available to us.

Despite our continued efforts over the last four years of delivering savings, there has been an increasing need to consider other areas including re-commissioning, reducing provision and disinvestment decisions. The significant in-year savings we are required to make will inevitably mean service changes.

Croydon CCG is aware of and committed to fulfilling our responsibilities under section 14Z2 of the Health and Social Care Act (2012). The CCG are also bound by the NHS Constitution and the rights of all patients to be involved in decision making processes which affect them. As an NHS body, the CCG has a responsibility to put patients at the heart of everything the CCG do and that the CCG are accountable to the public, communities and patients the CCG serve.

2. The Case for Decommissioning IVF and ICSI services

Croydon CCG commissions a NHS funded specialist tertiary fertility unit, to provide tertiary fertility services for assisted conception including Intra-cytoplasmic sperm injection (ICSI) and in-vitro fertilisation (IVF) fertility services including frozen embryo transfers (FETs) under a block contract the value for 2017/18 would be £887,595.

Under patient choice patients can opt to receive assisted conception at another NHS funded specialist fertility unit e.g. King's College Hospital, Guys and St Thomas' Hospital. In 2015/16 £72,442 was spent on IVF/ICS at other Trusts.

Croydon CCG currently funds one cycle for IVF with or without ICSI, for women under 39 years who have had unexplained infertility for at least three years.

Although there is NICE Fertility Pathway guidance, many other CCGs have recently implemented changes to their local policies following local consultations and in effect, reduced the scope and availability of NHS funded specialist assisted conception services as part of their QIPP plans. Nationally, four CCGs do not routinely provide funding for IVF and ICSI for their local populations.

All but one CCG in London offers one cycle of IVF+/-ICSI (Camden CCG offers three cycles). Only Wandsworth CCG in London has extended the age range for treatment to 42years. Nationally, a number of CCGs are reducing the provision of IVF cycles to one cycle in order to reduce expenditure or support an increase in the age range. Nationally there is also a variation in the number of frozen embryo transfers that are funded from unlimited down to no embryo transfers funded.

3. Criteria for consideration

In order to develop the proposals for making savings in NHS commissioning in the borough, Croydon CCG drew up assessment criteria that contains a number of domains and considerations in making these decisions. It is based on the NHS national priority selector. Each proposal was measured against the criteria before the CCG took them any further to ensure that all proposals are subject to rigorous assessment.

The assessment criteria have been co-produced with Croydon CCG's PPI Forum and include a range of questions for commissioners to consider under the following headings:

- patient benefit
- clinical benefit
- national priority
- local priority
- stakeholders
- buildings and equipment
- work-force
- service delivery
- financial benefit
- investment required
- future impact

Each scheme considered by the CCG as part of the Financial Savings Plan has been rigorously assessed against these criteria. The following section outlines how these proposals were assessed and therefore taken forward and presented to the public in the recent engagement process.

The prioritisation matrix is attached (Appendix C)

4. Assessment against the Criteria

On average, 94 couples are funded to receive treatment for assisted conception every year in Croydon. 188 residents equates approximately 0.047% of the population of Croydon.

On assessing this proposal against the CCG investment criteria, stopping routine funding will deliver financial benefits due to savings made from the decommissioning of the block contract and only funding through an Individual Funding Request process.

Nationally, the levels of service offered varies considerably, with four CCG's routinely offering no treatment, 1 of which has no defined exception criteria. IVF/ICSI treatment is widely available for self-funding patients, with costs varying between both private and NHS providers with self-funding routes. There is no national tariff for these treatments

After careful clinical consideration and discussion, IVF and ICSI has been put forward as a service that is of a lower clinical priority for Croydon than other services given the CCG's considerable financial challenge. The CCG acknowledges that while this proposal will affect a limited number of couples in Croydon each year, that impact to those couples has the potential to be great.

5. Service Information

Croydon CCG currently funds one cycle of IVF (with or without ICSI) funded cycle, with a maximum of two further frozen embryo transfers from the original harvest. These must be utilised within two years and are only available if the original treatment does not lead to a live birth.

Treatment for IVF is applied for through the CCG's Effective Commissioning Initiative (ECI) Policy and sometimes by Individual Funding Request (IFR) for exceptional circumstances.

As per Table 1, an average of 94 patients/couples received IVF/ICSI treatment each year for the past 4 years under the Croydon Health Services block contract. This equates to approximately 0.023% of the CCG population.

Whilst this is a very small percentage of the population, it is important to remember that this is a service that seeks to fulfil the parenting ambitions of couples. Therefore, a wider social value and socio economic benefit can be attached to the work beyond that of enriching the lives of those directly receiving treatment. This was very clearly conveyed during the consultation exercise. Points were made about population increases being economically important, familial support in older age saving money on care, and social value within communities.

Many more residents are engaged with the wider Fertility Service at CHS, with the service open to approximately 400 patients¹. This service is not funded from the IVF block contract and is not under consideration for decommissioning. These elements can be seen within the current care pathway below which is illustrated at Appendix A.

6. Current contractual arrangements

The current block contract has been in place since 2009. It has not undergone any significant review in that period. The table below shows the contract value per year and the number of completed cycles. NB this does not include failed cycles

Table 1: block contract costs/productivity

Year	Completed cycles	Block Contract value (including oocyte recovery)	Cost per cycle
2013-14	112	£807 490	£7 210
2014-15	86	£845 713	£9 834
2015-16	71	£820 199	£11 552
2016-17	108 (projected)	£845 249	£7 826
Average	94	£829 663	£8 803 Derived from total costs/total cycles

*data extracted from CSU SLAM cube

Definition of Cycle

A full cycle of IVF is one in which one or two embryos produced from eggs collected after ovarian stimulation are replaced into the womb as fresh embryos (where possible), with any remaining good-quality embryos frozen for use later. When these frozen embryos are used later, this is still considered to be part of the same cycle.

7. The options

The options below formed the basis of the public consultation. Other options around reducing costs were explored as part of the process but did not yield sufficient savings to make them viable.

1. No Change

Continue to fund IVF and ICSI under the existing Croydon CCG policy (2014/15 South West London Effective Commissioning Initiative, July 2014 ver. 1.6) and via the current block contract arrangement

This would maintain the IVF treatment for Croydon residents at cost in 2017/18 of £959 595 (assuming similar levels of cost with other providers to previous years). It would offer no savings toward the 2017/18 target of £36m.

2. Cease routine funding of IVF and ICSI services

There would be no funding for these services outside of the Individual Funding Request (IFR) mechanism for clinically exceptional circumstances. IFR is a well established process which considers in exceptional circumstances applications from a GP or consultant.

This would release savings of circa £281 000 for the year 2017/18 and circa £829 000 for 2018/19. This is due to the six month contract notice period as described above.

Risks and issues

Mental health impact - Not having access to IVF via the NHS could increase the number of infertile couples with anxiety, depression and relationship problems.

To mitigate this issues raised through the consultation consideration will need to be given to ensuring adequate access from commissioned mental health services to provide support.

Wider service effect - The fertility service at CHS will not be able to sustain itself without the block contract income. Therefore:

There would be no NHS provision within Croydon for those patients in the system who will qualify for continuation of their treatment under the existing criteria - currently circa 58 patients (Feb 2017). Arrangements may need to be made with other centres. The same issue will be relevant for any patients who qualify for IVF/ICSI due to exceptional circumstances (IFR) under the new criteria.

The wider fertility service at CHS which is not under consideration for decommissioning may close as a result of the potential removal of the block contract for IVF. This would lead to no provision for the circa 400 patients (Feb 2017) currently receiving treatment and gain provision would need to be accessed out of Borough if required.

To mitigate the above impact new provider/s would need to be found and contracted for the wider fertility service. Timescales are estimated to be between three and six months from notice being served to CHS. There are several providers in the local area that may be able to undertake this activity. The current providers are detailed in Appendix E.

Lack of public support for the proposal – If the proposal goes ahead, there will be a greater disparity between the provision for assisted conception and the current NICE guidelines. Public consultation reveals strong negative reaction to plans to stop this treatment particularly for those directly affected.

More expensive per case treatment – There will still be recourse to funding via the IFR mechanism for exceptional cases. It is possible that those treatments approved by the panel will be disproportionately expensive due to the low volume and therefore lack of commissioning power.

This would need to be mitigated by ensuring that alternative provision can be commissioned as required from alternative providers.

8. The National Context

Of the 209 CCGs in England, 125 CCGs fund one cycle of treatment. 46 CCGs fund two cycles of treatment and only 34 CCGs fund three cycles. 4 CCGs do not routinely fund any treatment.

Of those 4, 3 have defined eligibility criteria around certain conditions as follows (all taken from relevant CCG literature):

South Norfolk

- Patients undergoing cancer treatments
- Patients who have a disease or condition requiring a medical or surgical treatment that has a significant likelihood of making them infertile
- Couples who meet current eligibility criteria in which the male partner has a chronic viral infection where there is high risk of viral transmission to the female partner and potentially any unborn child (such as HIV or Hepatitis C), would also be offered ICSI.

Mid Essex

- Cancer patients who wish to preserve fertility before treatment
- Men who are HIV positive and where there is a high risk of viral transmission to their female partner

North East Essex

“only where there is a need to prevent the transmission of chronic viral infections, during conception, such as HIV, Hep C etc. which requires the use of ICSI technology. This is subject to patients meeting the eligibility criteria detailed below and in the North East Essex Fertility Services Policy.” (Criteria are age, bmi, smoking etc.)

Basildon and Brentwood

Basildon and Brentwood are the only CCG to currently not have any specified criteria, leaving the only path for treatment via an individual funding request.

“Clinically exceptional cases would be considered by application to the CCG’s Individual Funding Request Panel. The CCG would keep and monitor the impact of the change on both services and people with fertility problems. There would be a review of the policy annually and further changes could be applied, including a return to wider access to specialist fertility services, if this was considered to be affordable.”

8 Equality impact assessment

An Equality Impact Assessment was completed and the complete report is attached as Appendix D. In line with the report’s recommendation, the engagement process took into account the BAME profile of recent and current users and ensured that these communities were well represented in the consultation. Outreach was undertaken in areas of higher deprivation as recommended in the EIA. The report has recommended that women aged 18-39 and same sex couples should be allowed to submit IFR requests in line with any other group.

9 The findings of the public consultation feedback

An eight week period of consultation about the proposed changes to IVF took place between Wednesday 4 January 17 and Wednesday 1 March 2017. A formal consultation document and survey were developed, along with posters and leaflets. Throughout the consultation

period the CCG engaged face to face with over 330 Croydon residents, patients and professionals at two public meetings, and over 20 drop in and outreach sessions at different locations across the borough. A total of 467 written responses were received through the online or paper survey.

The main aims of consultation are to:

- gather opinion on proposed changes to the service
- understand the impact the change might have on Croydon residents
- identify ways to mitigate/lessen the impact of possible changes on patients and their families
- gather views and opinions as to what might form an exception criteria if routine funding ceased

The full findings of the consultation process should be read alongside this report which is attached at Appendix B.

The results of the on-line and paper survey indicated that:

The majority of respondents, 77 per cent, think Croydon CCG should opt to maintain one cycle of IVF for women 39 years old or younger. Just under a quarter of respondents, 23 per cent, think the CCG should stop the routine provision of IVF.

Survey respondents were asked if they had any specific concerns with the proposal to stop the routine provision of IVF. The main concerns were:

- The affordability of private IVF treatment and the impact on low income families
- Fertility as a right
- Unfairness of choosing to stop funding IVF
- Creation of a postcode lottery for IVF
- Impact on couples who cannot have children
- Impact on other services if IVF is decommissioned
- Impact on Croydon University Hospital IVF clinic
- Infertility as a medical condition is not being treated, whereas self-imposed lifestyle illnesses are
- The proposal is not in line with NICE guidelines

A summary of the key issues and the CCG response is provided below.

Issues	Response
Is it possible for the CCG to share funding of IVF treatment with patients or to part fund areas of the treatment, for example funding the fertility drugs?	The CCG has taken legal advice about the possibility of sharing cost with patients or means testing. It has been advised neither of these options are legal as they would contravene the central principle of the NHS: being free at the point of delivery, as stated in the NHS Act 2006.
A few patients are undergoing fertility tests, have had their treatment delayed or are waiting the required three years until they become eligible for treatment. If the CCG decided to stop the routine provision of IVF, could it provide clarification of the funding position for these groups?	The proposal does not affect those people who have already started IVF treatment or those whose referral forms have been received by the CCG and who meet the current criteria for funding. If the Governing Body decides to cease the routine provision of IVF, people who have yet to meet eligibility criteria of having been

	<p>actively trying to conceive for three years or who have not had their funding approved by the time the decision is taken and the waiting list closes would not receive NHS funding for treatment unless they are put forward as clinically exceptional and considered by the IFR panel.</p>
<p>The consultation survey asked if any groups should be exempt from the proposal to cease the routine provision of IVF. Could commissioners clarify how, in general, eligibility criteria ('exemptions' in the proposal question) are different to exceptional circumstances for Individual Funding Requests?</p>	<p>Currently, IVF has a set of eligibility criteria: women have to be 39 years old or younger, have been trying for a child for three years and have a BMI in the range of 19-30 kg/m². 'Exemptions' would become a defined set of eligibility criteria, for example have had cancer or be under the age of 30. Everyone meeting these criteria would be able to receive treatment.</p> <p>By contrast, the exceptional circumstances for Individual Funding Requests have no specific criteria. Instead, an exceptional clinical circumstance is one that suggests the patient is:</p> <ul style="list-style-type: none"> • Significantly different from the general population of patients with the condition in question; and • Likely to gain significantly more benefit from the intervention than might be normally expected for the average patient with the condition. <p>The fact that a treatment is likely to be effective for a patient is not, in itself, a basis for exceptionality.</p>
<p>Themes</p>	
<p>The affordability of private IVF treatment and the impact on low income families</p>	<p>The CCG understands the costs of private IVF treatment are high and may not be affordable for all couples. This is not a decision the CCG would choose to take if it did not have substantial savings to make.</p>
<p>Infertility is recognised as a disease by the World Health Organisation. There is a concern that Croydon CCG does not recognise infertility as a medical condition.</p> <p>There were also concerns that people with self-induced illnesses from poor lifestyle choices would have treatment fully funded.</p>	<p>The CCG is not questioning whether or not infertility is a medical condition. Given the need to make substantial savings, it has proposed other forms of healthcare take a priority over IVF services.</p> <p>Croydon CCG already places restrictions on access to certain services for smokers and people suffering from obesity. This includes access to IVF, where both partners have to have been non-smokers for six months prior to treatment and have a BMI in the range of 19-30 kg/m². It cannot legally cease the provision of urgent care for people with</p>

	lifestyle illnesses.
A further step away from NICE guidelines and creation of a postcode lottery.	NICE guidelines are not sets of rules about what should be commissioned. They are guidelines. The purpose of the CCG system is to determine local NHS priorities and to commission in line with these. With limited finances, the CCG cannot afford to commission all services in line with NICE guidelines. There are already variances around the provision of IVF across the country and it is likely other CCGs will be reviewing their local provision under budgetary pressures.
There were concerns about the potential increase in demand for mental health services resulting from the impact on infertile couples and possible increase in multiple births from overseas treatment	The CCG recognises the raised risk of mental health problems in those with infertility. The cost savings have been calculated taking account of the potential increased demand for mental health services but we would envisage these being accommodated within currently commissioned mental health services.
Concern a decision to stop the routine provision of IVF will result in the closure of Croydon University Hospital and require travel for Croydon residents who will need frequent appointments for IVF treatment	Croydon CCG is not the only CCG to use CUH fertility clinic. However, we recognise there is a concern about the viability of the CUH clinic if Croydon ceases funding IVF. We realise IVF can be an intense treatment requiring a lot of visits to the clinic, making local services desirable. Human Fertilisation and Embryology Association website allows a search for local IVF providers. It lists 20 providers within a ten mile radius.

As part of the consultation (full report Appendix B) responders and attendees to events were asked what, if any, exemptions should be defined if routine provision was discontinued:

“Most respondents did not suggest exemptions and it is important to note some people who did suggest exemptions stated they thought they would be unfair”

10. Governing Body Discussion and Agreement

The Governing Body at its meeting on the 14th March considered the feedback from the Consultation on the decommissioning of Assisted Conception Services and following this discussed and approved the recommendation to cease routine funding of Assisted Conception Services.

This decision would be implemented from the 14th March (except for applications received by 14th March which meet the approval criteria and approved cases on the waiting list).

The GB also noted and agreed the recommendation that in exceptional circumstances applications for Individual Funding Reviews (IFR) from a GP or consultant would be considered.

The GB also considered whether the CCG should specify any eligibility criteria exceptions or, as recommended, solely utilise the IFR process. It concluded that it would be difficult to agree any specific criteria and this also reflected the outcome of the public consultation.

The GB also agreed to continue to review the decision on an annual basis in line with other service priorities and the CCG's financial position.

This has been a very difficult decision for the Governing Body as it will result in a cohort of patients who will not receive NHS treatment and impact on the parenting ambitions of Croydon couples. However, it cannot be taken in isolation from consideration of the need to ensure continued provision of other higher priority services

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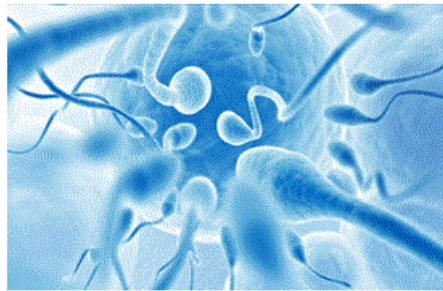
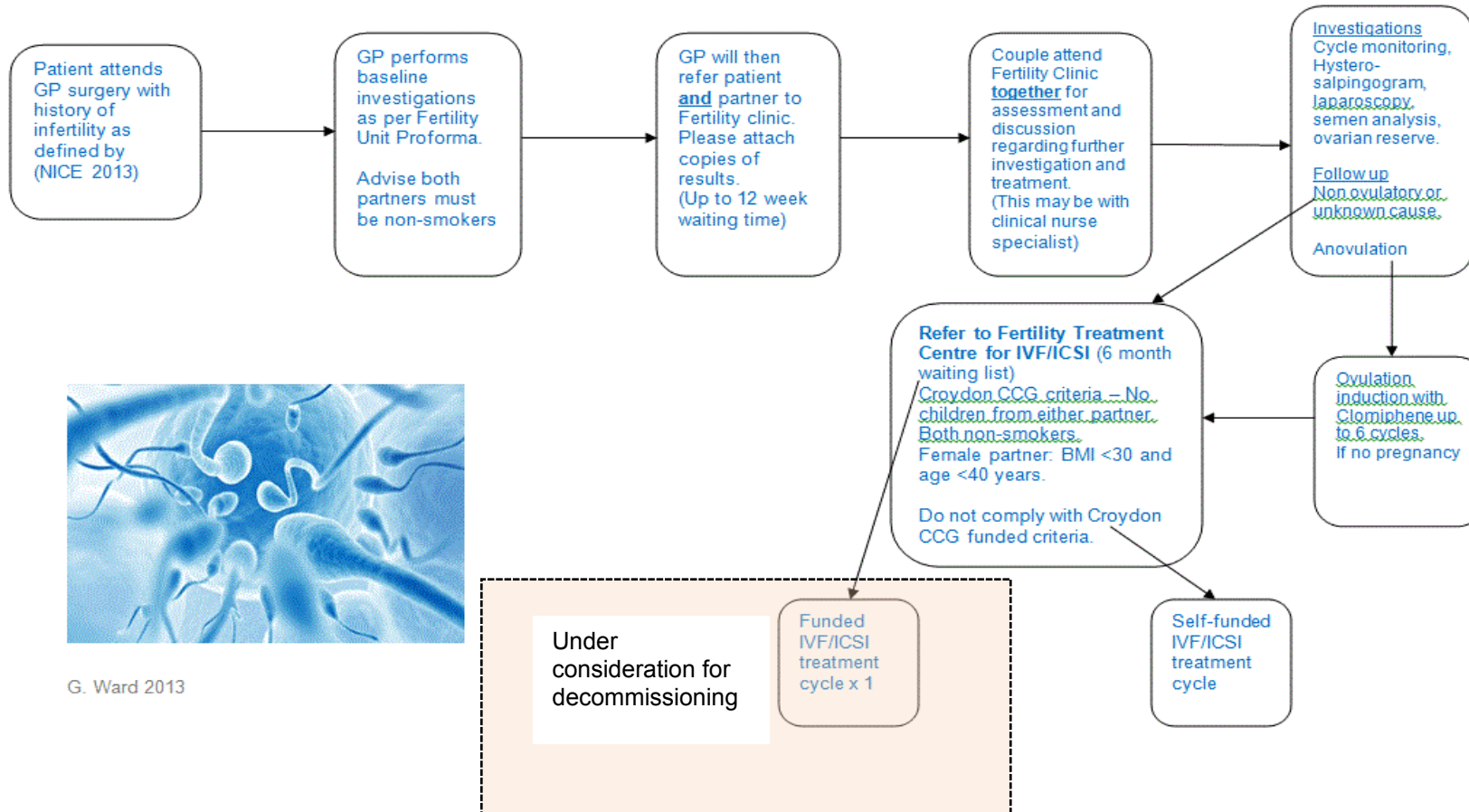
Associate Director – Planned Care Commissioning, Service Redesign and QIPP Development

Tom Cleary Commissioning Programme Lead

Thursday 16th March 2017

Appendix A: Current Pathway for Fertility Services at Croydon Health Services

Patient pathway



G. Ward 2013

