

TO: West Gloucestershire Primary Care Trust Board

FROM: Nicki Millin, Assistant Director of Service Development

DATE: 17th March 2005

SUBJECT: IMPLEMENTATION OF NICE FERTILITY GUIDELINES WITHIN GLOUCESTERSHIRE

1.0 PURPOSE

1.1 Cotswold and Vale PCT are the lead organisation in Gloucestershire for maternity services. As a part of this role they have led a working group looking at the implementation of NICE Clinical Guidance relating to fertility. Cotswold and Vale PCT have produced a paper for discussion at PCT Boards and this is attached. The inclusion criteria and proposed treatments have been previously discussed and agreed by the PEC.

2.0 BACKGROUND

2.1 NICE Clinical Guidance 11: Fertility assessment and treatment for people with fertility problems was published in February 2004. Guidance for implementation of the guideline states that eligible people should be offered one IVF cycle by April 2005. IVF is currently an Intervention Not Normally Funded (INNF) in Gloucestershire.

3.0 RECOMMENDATIONS

3.1 The Board is asked to discuss the attached paper and agree the recommendations for implementing the NICE fertility Guidelines in Gloucestershire.

Report to the Trust Board to be held in March

1. Title of Report	NICE: Fertility Guidelines. Implementation across Gloucestershire
2. Introduction	NICE Clinical Guideline 11 relating to Fertility was published last February (2004). John Reid (Health Minister) asked for all PCT's to introduce 1 cycle of IVF per eligible couple by April 2005. A working group was established to formulate an implementation plan for Gloucestershire to introduce the minimum service for 2005/6 and a longer term business plan for fertility to go to Boards in Autumn 2005.
3. Summary of the issues	
Key points	County wide agreement to introduce for eligible couples from April 2005: <ul style="list-style-type: none"> • 1 cycle of IVF • Up to 6 cycles of ovulation induction • Up to 6 cycles of donor insemination [The latter 2 treatments need to be funded otherwise these couples could persue the IVF route.] NICE suggest that criteria should be used relating to age, body mass, smoking, etc and PEC is asked to agree the proposed local criteria for 2005/6.
Key implications	Finance: Assisted fertility has not historically been funded for specific treatments and so there are financial consequences. Numbers for treatment: This is best estimate based on published papers, NICE information and local health needs assessment. It is dependent on criteria used, ad the number of women who would have persued this route had funding previously been available.
Costs/Funding	Up to £750,000 across county based on historical data and allowing for 'backlog'. It is assumed that by applying the local criteria this would be greatly reduced.
4. Key Risks	Of implementing: Finance: the above figure is the uppermost sum likely to be needed. Waiting times: for outpatients at GHT and tertiary providers may be increased. Multiple pregnancies: Approx 25% of successful IVF pregnancies lead to twin pregnancies and 2% have triplet pregnancies. Neonatal cots (NICU): it is anticipated that approx. 20% of successful assisted fertility treatments require admission to NICU. This information is currently not collected routinely, and it is anticipated that 2 babies per month may require this service. It is likely that some babies already are admitted to NICU following private treatment. The level of dependency in NICU is also not known. Higher dependency maternity: Women who have undergone assisted fertility are at an increased risk of pre-eclampsia and other conditions. Of not implementing: Complaints/Litigation: The extent of this is unknown.
5. Legal Advice	This was sought from Bevan Brittan LLP and they advise to publish the policy with robust supporting evidence for its reasonableness in place. The policy is in draft form and comments are welcome.

6. Recommendation	The Board is asked to agree: <ul style="list-style-type: none">• the above treatments of 1 cycle of IVF, up to 6 cycles of ovulation induction and donor insemination• the policy (attached)• the implementation plan (Attached)• to review the implementation criteria and outcomes later in the year.
--------------------------	---

Policy on Assisted Fertility

1.0 Purpose

This policy sets out the process by which couples can access assisted fertility techniques.

2.0 Background

Gloucestershire Health Community has, historically, not funded many assisted fertility techniques. The small volume of assisted fertility techniques that have been funded are as Interventions not normally funded (INNF).

The publication of the NICE Clinical Guideline 11: Fertility: assessment and treatment for people with fertility problems ¹ in February 2004, raised many challenges for the health community. The Health Minister, John Reid issued a statement ² which outlined that all PCT's should implement 1 cycle of In Vitro Fertilisation (IVF) for all eligible couples from April 2005.

In accordance with these documents a working group was established and with support from the Professional Executive Committees (PEC's) of the 3 Primary Care Trusts (PCT's) have agreed the following process. The working group are continuing to work on a longer term business plan. The working group recommend that this policy is reviewed after 1 year.

3.0 Assisted Fertility Treatments

Following discussions within Gloucestershire health community it was agreed that we implement assisted fertility treatments for eligible couples from April 2005 which include:

- 1 cycle of In Vitro Fertilisation (IVF)
- up to 6 cycles of ovulation induction
- up to 6 cycles of donor insemination

4.0 Inclusion Criteria

The following criteria (Table 1) should be applied to all couples seeking assisted fertility treatment. These criteria are drawn from NICE Clinical Guideline 11 or from John Reid's statement.

It is difficult to ascertain the exact numbers of couples likely to seek treatment in the first year as it is recognised that there may well be couples who are waiting for NHS treatment as well as couples identified as requiring assisted fertility treatments from April 2005. The Public Health department at Cotswold and Vale PCT ³ have undertaken some work and the number of couples likely to seek treatment by PCT can be found in Appendix 1.

The criteria have been formulated after considering resources available. Resources considered are:

- number of neonatal cots,
- capacity within the tertiary sector,
- potential higher dependency maternity care
- financial costs.

Table 1: *Areas subject to review for next financial year.

Criteria Aspect	Covering	Additional information
Age (Woman's)	30-39 years*	Age at time of first treatment
BMI (Woman's)	19-30	
Period of failing to conceive (Couple)	3 years	Unless known cause e.g blocked fallopian tubes Special exceptions may be referred to PCT's for INNf
No living children (Couple)	ALL*	Special exceptions may be referred to PCT's for INNf
Smoking	No	Refer to smoking cessation (GSAS)
Previous IVF Treatment	None*	No previous NHS funded IVF or 3 cycles of private IVF
Residential Area	ALL	Registered with a Gloucestershire GP
HFEA Codes of Practice ²	ALL	

5.0 Process

The attached implementation plan (Appendix 2) will be used for all couples.

Couples with a history of fertility issues would seek support from their G.P who would refer into secondary care as appropriate using an agreed template. It is expected that all basic investigations would have been undertaken in primary care as is current practice.

Onward referral would then be made to tertiary providers by secondary care consultants. A copy of this tertiary referral will be sent to the PCT from where the couple reside and copied to Cotswold and Vale PCT.

When the number of couples, seeking assisted fertility treatments, are identified as greater than 10 couples per month, a contingencies group will meet to prioritise the 'waiting list'. This group will be drawn from members of the working group with each PCT represented.

6.0 Monitoring:

It will be necessary to audit the outcome of women undergoing fertility treatment with respect to outcome and neonatal intensive care usage.

7.0 Finance Issues.

Cotswold and Vale PCT will receive the invoices and recharge the other PCT's as agreed.

8.0 Appeals

Any couples seeking assisted fertility treatments who do not fulfil the criteria can seek funding through an INNf appeal.

References:

1. NICE (2004). NICE Clinical guideline 11. Fertility: assessment and treatment of women with fertility problems.
2. DOH (2004) Reference number 2004/0069. Health Secretary welcomes new fertility guidance.
3. Cotswold and Vale PCT (2004). Fertility Public Health

APPENDIX 1

Data from health needs assessment³

PCT	Cases of fertility 23-39	48% IVF	If 70% couples are childless	30-39 years	If 30% BMI greater than 30	Apply conception rate of 0.1	Stimulated IUI in IVF	Ovulation Induction in IVF
Cheltenham& Tewkesbury	888	426	298	182	127	12.7	4.43	4.75
Cotswold and Vale	939	451	316	215	151	15.1	5.74	6.18
West Gloucestershire	1206	579	405	267	187	18.7	7.07	7.58
Gloucestershire	3033	1456	1019	664	465	46.5	17.24	18.51

3. Cotswold and Vale PCT (2004). Fertility Public Health

NICE Clinical Guideline 11: Fertility Implementation Plan

The working group have drawn up an implementation plan for couples experiencing fertility issues.

1. It is expected that couples experiencing difficulties will arrange to see their G.P.
2. A standard referral template will be used by all G.P's for onward referral to secondary care. This will have any results of investigations undertaken by the G.P. to ensure appropriate and effective referrals.
3. All women will be seen at identified fertility clinics in either Cheltenham or Gloucester within the waiting list timescale.
4. Appropriate investigations will be undertaken and interventions identified as appropriate.
5. Where IVF, ovulation induction (OI), or donor insemination (DI) are identified as appropriate interventions, the secondary care provider will complete another referral template and forward to a central access point.
6. The central access point will manage all referrals for tertiary care. Where more than 10 couples per month are identified as needing tertiary care, a contingencies group will meet to prioritise the 'waiting list'. This group will be drawn from members of the working group with each PCT represented.
7. All couples will be seen by tertiary care within 6 months of their name being forwarded to the central access point.
8. Tertiary care providers will be identified using commissioning principles applied to other disciplines. It is anticipated that Bristol, oxford, Birmingham and London will be the main tertiary providers with the majority of couples choosing Bristol and Oxford. At present these are from the independent sector.
9. Tertiary care providers will liaise with G.P's to ensure the Welfare of the Child letter is completed prior to commencement of active treatment.
10. Treatment will be provided by tertiary care.
11. When a pregnancy is achieved the couple will enter the usual maternity care pathways.
12. All outcomes will be collated on women referred to tertiary care.

NICE Clinical Guideline 11 Fertility Implementation Plan Chart 2005/6

