

The last few years have seen the increase in the number of couples that now feel able to start a family. This in main has been the result of the advances in medical science. The implication for the Trust is that more and more of its registrants will be and have been making request, for financial help in assisted fertility treatment. Although it could be argued that this is not a direct health issue. In the sense that it is not related to the physical health of the registrants it is in fact a mental health issue and as such will and can lead to problem of the relating to physical health.

Up until 1998 The Trust supported inseminations by donor treatment to enable couples to have children. This was discontinued as Trustees at the time believed the National Health Service should fund such treatment. Given an 'ideal world' this would be the case. Unfortunately this is not an 'ideal world' and the support for this treatment will depend on which NHS area the couples live in and their ability to access the relevant individuals so as to get the support required for funding. This process also needs to be completed before the couples have got to the age that is considered too old to be placed on the programme.

Most of the couples that have contacted the Trust making request for financial assistance, have already approached their NHS and have been informed that there are no funding available or that the waiting time/list for this treatment is 18 months or more. This obviously then leaves these couple with a dilemma, can they afford to wait or do they seek alternative means of funding?

Given the fact that their specific health condition, will means that the window of opportunity available to do this can be very short, they then do not have the luxury of unlimited time, so getting funding is a matter of some urgency and importance.

Although it is not the policy of the Trust to give financial assistance to couple wishing to have assisted conception treatment. This is a matter that requires great thought and consideration without any individual biases attained to it. When the Trust was originally set up, the individual members as they were known at the time were not considered to have a future. This has proven not to be the case and therefore, as implications regarding funding, this is one of the areas that require addressing.

The other future implication is that the Trust also has a young population, who will at some stage be considering the need for this form of help and support to enable them to exercise their right to choose to have a family. This, been the case addressing this issue is something that should no longer be delayed. As it is quite apparent that this is another postcode type issue.

RECOMMENDATION:

That the Trust gives support to the individuals that are making request for this treatment. That as it is a costly treatment it is restricted to 3 treatment only. This would also then fall in line with the NHS trusts that are giving assistance.

That there is a limit placed on the numbers of application the Trust can accept in any one financial year.

Claudette Allen
Social Worker

Attachment- NAM factsheet 53

C & W NHS TRUST Price list 2001

P & C Letter to Dr Christine Lee

C & W NHS TRUST information sheets

sperm washing

Sperm washing is a process which has been developed for couples who wish to have a child, where the male is HIV-positive and the female is HIV-negative. The procedure reduces the risk of HIV transmission to the female partner and subsequently the unborn child.

Sperm washing rests on the premise that HIV infected material is carried primarily in the seminal fluid rather than in the sperm itself. The technique involves purifying sperm from seminal fluid. The sperm is then used for insemination into the female partner when she is ovulating and most likely to become pregnant (called Intra-Uterine Insemination or IUI), or for in vitro fertilisation, (IVF).

This technique was pioneered in Milan. To date the programme in Milan has undertaken more than two thousand inseminations and several hundred IVF cycles. So far, none of the women has seroconverted and all of the children born have tested HIV-negative. The eldest child is now eleven.

There remains a very small theoretical risk to the woman of HIV transmission. Sperm washing is however, considerably safer than having unprotected sex, but if a couple is certain that they don't want to take any risk, no matter how minimal, sperm washing would not be a suitable method for them. These couples may prefer to find out more about artificial insemination by donor which is a risk free alternative.

A sperm-washing service is available at the Chelsea & Westminster (C&W) Hospital, and is discussed here as an example. Other centres may also offer this service. A couple's first step on the C&W programme is to see a counselor, to get further information and support, and to explore some of the issues involved. Partners are seen individually and together. Deciding to embark on this treatment may not be a easy decision. Although the risk of the female partner becoming infected is minimal, it still exists, and for one or both partners it may be felt that this risk is too much. There is also an opportunity to discuss issues concerning parenting itself, coping with a child when one parent is HIV-positive and facing the reality that treatment does not guarantee pregnancy. Counseling is available on an individual and couple basis throughout the time on the C&W programme.

During the first visit, couples will also need to have a full sexual health screen which includes an HIV test for both partners.

Following these tests, an appointment is made with the C&W Assisted Conception Unit who will assess the fertility of each couple. Over the following few weeks, tests including various blood tests along with an ultra-sound scan and an x-ray for the female partner, and a semen analysis for the male partner will be performed. These tests indicate whether insemination would be a realistic option. If either partner was to have sub-optimal fertility, IVF may be a consideration after all avenues have been explored. All preliminary investigations and appointments can take two to three months.

Acceptance criteria of the C&W programme

Couples need to provide a referral letter from their doctor (either GP or HIV doctor), and current information concerning viral load and CD4 count. The C&W Assisted Conception Unit is obliged to consider the welfare of any child that might be born as a result of their intervention. They are only able to offer the service to couples who are in a stable and committed relationship.

Couples are asked to sign a consent form which states that both partners understand the procedure and are prepared to accept the minimal risk involved.

The female partner is obliged to have regular HIV tests throughout the programme. It is imperative that couples do not have unprotected sexual intercourse for the preceding 3-6 months before entering the programme and for its duration. Both partners must also abstain from any other high risk activities that could put them at risk of HIV or any other blood borne infections.

Costs

There is a cost attached to sperm washing, which as yet is not available on the NHS. Individual health authorities may be approached on the basis of risk reduction. Some health authorities are sympathetic and may agree to fund one or several cycles of IUI with sperm washing. Currently the cost of initial tests and consultations in the C&W programme stands at £570. Each cycle of IUI with sperm washing is £750.

All enquiries regarding the C&W sperm washing programme should be directed to the Assisted Conception Unit (telephone 020 8746 8234).

Credit: Helen Rivas-Torro and Dr Jill W Gilmour

PLEASE PHOTOCOPY AND PASS ON

NAM publishes a wide range of publications on treatment for HIV

for details write to
NAM
Freepost LON277
London SW4 7AB

telephone
020 7627 3200
or visit
www.aidsmap.com

ASSISTED CONCEPTION UNIT

Tel: 020 8746 8585

Fax: 020 8746 8921

e-mail: acu@chelwest.nhs.uk

Chelsea and Westminster Hospital
369 Fulham Road
London
SW10 9NH

Tel: 020 8746 8000

PRICE LIST 2001

Initial Consultation	£115
Follow up Consultation	£80

In Vitro Fertilisation (IVF) Package	£1750
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This is inclusive of:

- Pre treatment semen analysis
- Pre treatment LH/FSH/progesterone blood tests
- Pre treatment baseline ultrasound scan
- Counselling
- Follicle Tracking and Nurse led Consultations
- Egg Collection under Sedation
- Embryo Transfer
- 2 Early Pregnancy Scans
- Follow up Consultation
- HFEA Cycle charge

Intracytoplasmic Sperm Injection (ICSI) Package	£2350
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As for IVF but using the ICSI technique

Ovum Donation (OD) with IVF/ICSI Package	£2400/£3000
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This is inclusive of:

- Pre treatment semen analysis
- Pre treatment baseline ultrasound scan for both yourself and the donor
- Appropriate blood tests for both yourself and the donor
- Counselling for both yourself and the donor
- Follicle Tracking and Nurse led Consultations for both yourself and the donor
- Egg Collection for the donor
- Embryo Transfer
- 2 Early Pregnancy Scans
- Follow up Consultation
- HFEA Cycle charge

Frozen Embryo Donation	£1250
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Intra Uterine Insemination per cycle	£400
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This is inclusive of:

- Pre treatment semen analysis
- Pre treatment LH/FSH/progesterone blood tests
- Pre treatment baseline ultrasound scan
- Counselling
- Follicle Tracking and Nurse led Consultations
- Semen preparation and Insemination

Frozen Embryo Transfer per cycle	£400
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This is inclusive of:

- Counselling
- Follicle Tracking and Nurse led Consultations
- Thawing and Transfer of embryos

Please note that the above prices do not include drugs that you may require.

Director: Dr Carole Gilling-Smith, PhD, MRCOG
Laboratory Director: Dr Paula Almeida, PhD

Male Infertility Specialist: Mr Jonathan Ramsay, MS, FRCS
Sister: Jane Holman, RGN, Dip Fert

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Tel: 020 8746 8585
Fax: 020 8746 8921

e-mail: acu@chelwest.nhs.uk

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Tel: 020 8746 8000

Additional Charges if required:

Semen Freezing	£200
• Includes first year storage	
Annual Semen Storage	£100
Embryo Freezing	£250
• Includes first year storage	
Annual Embryo Storage	£150
Chromosome Analysis	£110
Donor Sperm for 3 vials	£150-£180
• Variation Dependant on Ethnic Origin of Sperm	
• Includes courier charges	
Immunology Charges for Sperm Washing	£350
• Extra charge per cycle of IUI/IVF/ICSI	
Abandoned IVF/ICSI/OD/FET/IUI Cycle Charge	£300
• When had 2 or more ultrasound scans	

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Chelsea and Westminster ACU Updated June 2001

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SPERM WASHING PROGRAMME PRICE LIST 2001

Initial Work Up £570

This is inclusive of ;
Appointment at John Hunter Clinic
Counselling
Sexual Health Screen
Appointment at Assisted Conception Unit
Fertility Screening Tests
Review Consultation at Assisted Conception Unit

Follow up Consultation £80

Intra Uterine Insemination per cycle £750
This is inclusive of:

- Counselling
- Follicle Tracking and Nurse led Consultations
- Sperm Washing
- Insemination

In Vitro Fertilisation (IVF) Package £2100
This is inclusive of:

- Counselling
- Follicle Tracking and Nurse led Consultations
- Egg Collection under Sedation
- Embryo Transfer
- 2 Early Pregnancy Scans
- Follow up Consultation
- HFEA Cycle charge
- Sperm Washing

Intracytoplasmic Sperm Injection (ICSI) Package £2700
As for IVF but using the ICSI technique

Chromosome Analysis £110

Abandoned IVF/ICSI/OD/FET/TUI Cycle Charge £300
• When had 2 or more ultrasound scans

Director: Dr Carole Gilling-Smith, PhD, MRCOG
Laboratory Director: Dr Paula Almeida, PhD

Male Infertility Specialist: Mr Jonathan Ramsay, MS, FRCS
Sister: Jane Holman, RGN, Dip Fert

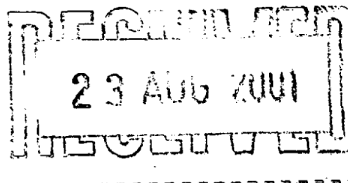
Primary Care Trust

No: 1319

Luton Primary Care Trust
Nightingale House
94 Inkerman Street
Luton
Beds
LU1 1JD

Tel: 01582 528840
Fax: 01582 528841

Private & Confidential
Professor Christine Lee
Professor of Haemophilia
Royal Free Hampstead NHS Trust
Pond Street
London
NW3 2QG



GRO-C

Ref: OAT404/rw

18th August 2001

Dear Professor Lee

Re: Patient M O, dob GRO-A/79

Further to your letter dated 16th July to Regina Shakespeare, I am writing to give approval for the above patient to undergo sperm washing treatment, as outlined in your initial out of area treatment application dated 16th May 2001.

Luton PCT will agree the funding for a 'one-off' treatment only. Also the PCT has not agreed funding for any subsequent IVF treatment. Funding is approved on this basis only.

If you would like to discuss these issue with me please feel free to contact me.

Yours sincerely

GRO-C

Laura Guest
Director of Health Improvement & Commissioning

Luton Primary Care Trust
Nightingale House
94 Inkerman Street
Luton
Beds
LU1 1JD

Tel: 01582 528840
Fax: 01582 528841

Private & Confidential

Ms Christine Lee
Professor of Haemophilia
Royal Free Hampstead NHS Trust
Pond Street
London
NW3 2QG

GRO-A

Ref: OAT357/dh

15th June 2001

Dear Ms Lee

Re: Patient M O, dob GRO-A79

Your letter of 16th May addressed to Bedfordshire Health Authority, in relation to a request for an out of area treatment for the above patient, has been forwarded to Luton Primary Care Trust for consideration.

Our Chief Executive, Regina Shakespeare is the point of contact for requests of this nature. However, she is currently on annual leave. In her absence we are seeking advice from the Public Health Department at Bedfordshire Health Authority and will contact you again in the near future.

Yours sincerely

GRO-C

Dee Hogan
Executive Assistant

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Fax: 020 8746 8921

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Tel: 020 8746 8000

SPERM WASHING AN HIV TRANSMISSION RISK REDUCTION TECHNIQUE

*Information on planned pregnancy between HIV discordant couples where
the male is HIV positive and the female is HIV negative.*

This service has been developed for couples who wish to have a child, where the male partner is HIV positive but the female is HIV negative (referred to as HIV discordant status). The aim is to reduce the risk of HIV transmission by attempting to achieve pregnancy through insemination of sperm washed free of HIV rather than through unprotected intercourse. The technique used to do this is called sperm washing and rests on the premise that HIV infective material is carried in the fluid around the sperm (seminal fluid) rather than by sperm itself. The technique involves separating the HIV infected seminal fluid from the sperm by centrifugation and 'washing'. The 'washed' sperm is then combined with nutritional fluid, tested for HIV using a sensitive test called a 'PCR' assay and, provided this is negative, inseminated into the female partner when she is ovulating and most likely to become pregnant.

Only a handful of clinics in Europe, including our own at the Chelsea & Westminster Hospital, provide this service which was pioneered by Dr Semprini in Milan over ten years ago. To date, over 3000 inseminations have been carried out in these different centres and over 300 healthy HIV negative children have been born. To date there have been no reported cases of HIV infection in either the female partner or child following sperm washing, which is convincing evidence that this technique does indeed provide a significant risk reduction over unprotected intercourse. Current estimates would suggest the risk of HIV transmission per act of unprotected intercourse is 1 in 500. Most couples attempting to conceive naturally need to multiply this risk by at least a factor of 10, providing both are fertile. This is because fertile couples usually take between 3 and 6 months to conceive so an HIV discordant couple will likewise probably need to have unprotected intercourse over a similar time period. If there are any undiagnosed fertility factors the risk will be far higher as the couple may continue to have unprotected intercourse for much longer.

Given these data, sperm washing should be regarded as a risk reduction option for couples attempting to conceive, but not as a guaranteed absolutely risk-free technique. This is because although the washed sperm is tested for HIV before insemination, the most sensitive PCR test available we use (called NASBA) will only detect HIV if there are more than 50 copies of the virus per 10 million sperm (this is called the detection limit of the assay). However it is far safer than having unprotected sex at mid-cycle.

If you feel that you do not want to take any risk, no matter how minimal, sperm washing should not be contemplated. You may prefer to find out more about artificial insemination by donor, which is a risk-free alternative.

**020 8746 8234 is a dedicated line for the sperm washing programme.
Please ensure that you always use this number when contacting the unit.**

THE SPERM WASHING PROGRAMME

The Sperm Washing team

The programme is led by Dr Carole Gilling-Smith who is a Consultant Gynaecologist and Director of the Assisted Conception Unit at the Chelsea & Westminster Hospital. The team is multidisciplinary and involves a nurse co-ordinator, embryologists, immunologists, ultrasonographers and sexual health counsellors. The stages involved in the programme are summarised below and in appendix 1.

Referral

If as a couple you would like to embark on the programme, you should obtain a letter of referral from your HIV physician, which summarises the medical history of the infected male partner (including details on length of infection, current viral load and CD4 count and medication).

1st Appointment - John Hunter Clinic

Once we have received this letter, our sperm washing co-ordinator will contact you and ask you to make your first appointment. This will be in The John Hunter Clinic, next door to the main hospital. The purpose of this visit is for you both to receive more information and counselling about the treatment and risks involved and for you both to have a full sexual health screen.

Pre-Conceptual Counselling

We have included counselling in the programme to allow you both to get further information and support and explore some of the issues involved in the treatment. We like couples to be seen together and individually before they make the final decision to go ahead with treatment. Deciding to embark on sperm washing is not always an easy decision for couples. Although the risk of the female partner becoming infected is minimal, it still exists. You should therefore both be prepared for this eventuality and you may also wish to discuss issues concerning parenting itself, coping with a child when one parent is HIV positive, and facing the reality that treatment may not result in a pregnancy. Counselling will be available on an individual and couple basis throughout the time you are on the programme.

Sexual Health Screen

The counsellor will discuss the different investigations which need to be done prior to insemination. The tests you need include having genital swabs taken and a blood test for hepatitis B and C. The female partner will also be required to have an HIV test. The table in appendix 2 gives the full list of tests required and some of these can be done locally prior to your first appointment. Those not done locally will be done at the John Hunter clinic on your first visit. You will be seen first by a doctor and then a nurse will perform the tests. The results of all the tests will be given in a follow-up appointment at the John Hunter Clinic approximately one week later.

2nd Appointment - Assisted Conception Unit

After your follow-up appointment in the John Hunter Clinic, you will then see Dr Carole Gilling-Smith. She will take a full history from both of you and arrange the fertility screening tests required (see appendix 2) to ensure that insemination has a good chance of working. She will also explain the sperm washing and insemination procedure and the small risks involved with the technique. She will then arrange for you to have the various tests to take place over the next few weeks.

3rd appointment - Assisted Conception Unit ***Discuss fertility screen and plan treatment***

Once you have completed your investigations you will see Dr Gilling-Smith for a follow-up appointment. She will review the results of all your tests. If these are satisfactory (see criteria for insemination in appendix 2), she will advise you as to when it will be possible to start insemination treatment. If fertility factors are revealed she will advise you on further investigations required and/or treatment options that can be combined with sperm washing such as in vitro fertilisation (IVF) or intracytoplasmic sperm injection (ICSI).

Sperm Washing and Intrauterine Insemination (SWP/IUI) - the treatment cycle

You will be asked to call the ACU on the first day of the female partner's next menstrual cycle in order to book an appointment for a follicle tracking scan for SWP/IUI treatment on day 8 or 9. Scans will then be carried out every two or three days to observe the growth of the lead follicle (a maximum of three scans are anticipated). Once the lead follicle is at least 17 mm in diameter, and the uterine lining is of a satisfactory thickness your insemination day will be planned for 48 hours later. You will be advised to have an injection of hCG (Human Chorionic Gonadotrophin or Profasi) to achieve final maturation and release of the egg. Ovulation will then occur approximately 36 hours after this injection and you will be asked to come back within that time for the insemination.

On the morning of insemination, the male partner will be asked to attend the ACU at 8 am to produce a sperm sample. The sample may be brought from home (ensuring that it is brought in within the hour and is kept warm) or a designated room may be used at the hospital. It will take a few hours to prepare and wash the sperm (see appendix 3). Once the sperm has been washed, it will be tested for HIV using the PCR assay to see if there is any detectable HIV. If HIV is detectable then your insemination will be cancelled. We advise our patients that the risk of cancellation on the day of insemination due to the sample testing positive is 5-6% (based on both our own and published data). Couples would still be liable to pay the full cost of the insemination treatment. We offer the option of the male partner providing two semen samples on the proposed day of insemination which can be washed and test concurrently. This would reduce the odds for a cycle being cancelled and couples being disappointed, as the chances of both samples testing positive following washing are extremely low.

If there is no detectable HIV we will be able to perform the IUI later the same day with the prepared sperm. The experience of the procedure is similar to that of having a cervical smear, the cervix is gently cleaned and then a small catheter is passed through the opening of the cervix and the sperm slowly injected in. When you go home, there is no reason not to carry on with your usual daily routine. Two weeks later you need to do a pregnancy test and inform us of the result. Appendix 4 summarises our programme's results as well as those from Dr Semprini's clinic in Milan. On the basis of these data we quote a 10% chance of having a baby (live birth rate) per insemination with washed sperm.

What are your responsibilities during the programme?

It is imperative that you do not have unprotected sexual intercourse for the preceding 6 months before entering the programme and for its duration. Both of you must also abstain from any other high risk activities that could put you at risk of HIV or any other blood-borne infections. The female partner will have regular HIV tests every 3 months throughout the programme, up to one year after her last assisted conception treatment.

Before starting investigations we will ask you to sign a consent form which states that you both understand the procedure and are prepared to accept the minimal risk involved. In the event of any woman, or child born as a result of this treatment, testing HIV antibody positive, the Chelsea & Westminster Healthcare NHS Trust cannot be held responsible.

How long will you be involved with this programme?

This is very difficult to assess. All preliminary investigations and one insemination will take approximately between 3 and 6 months from your first appointment. However, more than one cycle may be required if insemination is not successful and therefore this time may be extended. If the female partner has had unprotected sex with her partner within the past 6 months, or has been at risk to HIV through other high risk activities, it would be necessary to wait until 6 months had elapsed beyond this event. An HIV antibody test would then need to be done and providing the result was negative we would start the preparatory investigations.

Will all couples be offered treatment irrespective of their circumstances?

Each couple will be assessed on an individual basis regarding their suitability to the programme. We expect couples embarking on this type of treatment to be in a long-term, stable, monogamous, heterosexual relationship.

If either of you is currently using opiates and/or other addictive drugs on a regular basis you will need to be assessed by a Drug Dependency Unit (DDU). Individuals on a controlled methadone maintenance programme will also need to be assessed by their DDU. We would not envisage starting you on the programme until you were no longer taking drugs or controlled medication for at least 6 months.

APPENDIX 2

INVESTIGATIONS REQUIRED PRIOR TO INTRA-UTERINE INSEMINATION (IUI)

After receiving a letter of referral, we will ask your doctor to supply us with any recent, documented tests and results so that we don't duplicate any tests and procedures unnecessarily. The only exception to this is the female partner's HIV test and the male partner's semen analysis, both of which need to be carried out at the Chelsea & Westminster. The following section lists the tests that are required prior to IUI, whether they are carried out here or with your local doctor.

Sexual Health Screen in John Hunter Clinic

History
Examination

Male:

Gonorrhoea
Syphilis
Chlamydia

Viral load, HIV antibody 1 and 2, Hepatitis B and C status will be provided by referrer

Female:

HIV antibody 1,2
Hepatitis B
Hepatitis C
Trichomoniasis
Candida
Gonorrhoea
Syphilis
Chlamydia
Bacterial vaginosis

Fertility Screen in the Assisted Conception Unit:

Female:

FBC
Rubella
Prolactin
Thyroid Function
FSH, LH, E2 (day 2-5 of cycle)
Baseline pelvic ultrasound scan (day 2-5 of cycle)
Ovulation check (mid-luteal progesterone)
hysterosalpingogram

Male:

Semen analysis

Criteria for IUI/SWP treatment:

Female:

Normal pelvic scan
FSH not greater than 12,
ovulation confirmed
at least one tube confirmed patent on HSG

Male:

Semen analysis more than 20 million per ml, less than 80% abnormal sperm, more than 50% motility with good forward progression.