National Specialist Guidelines for Investigation of Infertility

Priority Criteria for Access to Public Funding of Infertility Treatment

In 1997/98 the publication of the National Health Committee's consultation document "Access to infertility services: development of priority criteria" received numerous public and professional submissions, almost all being in favour of the general principles that fair and equitable access to publicly funded treatment could be achieved by these criteria. These criteria have been tested in at least 2 NZ tertiary centres and, with minor modifications, the original proposal is being presented to the HFA to introduce to the NZ Health system.

This document is not about directing therapy. It is about guiding the evaluation of the infertile couple to achieve a standardised diagnosis and then providing a rationing basis for public access for treatment, especially using the assisted reproductive techniques. It is intended to benefit those who are most in need for therapy, but balanced by a system that will ensure maximum benefit. The actual level of access will be dictated by the proportion of public funds available for treating infertility. Evaluation of the pilot application of these criteria for IVF funding have, however, confirmed the view that infertility services are severely underfunded. We see these criteria as an essential step in establishing the level of funding needed for infertility treatment and request that Health Practitioners, working with the criteria, use them with diligence and honesty. Already the HFA has declared its support by providing significant funding to assist in clearing the waiting lists for Assisted Reproduction.

We emphasize that the application of these criteria and their weighting is just the beginning. The criteria need to be validated by ongoing research and public discussion.

Wayne R Gillett, John Peek, July 1999

GYNAECOLOGY / INFERTILITY

SECTION 1

Investigation and Diagnosis – a Standardised Approach

Investigation in Primary Care

Refer to National Referral Recommendations: Gynaecology; Infertility

Investigation in Secondary Care

As for primary care. In addition:

- A post–coital test may be used in the early investigation of a referred couple, but the results should be interpreted with caution. Performance of this test is not essential to complete the diagnostic categorisation of the couple (see diagnostic categories).
- Screening for anti-sperm antibodies is not a routine test, but is suggested when there is a history of testicular trauma or vasectomy reversal. Performance of this test is not essential to complete the diagnostic categorisation of the couple.
- Sperm function tests and sperm assessment procedures (e.g. swim-up tests) should not be used in secondary care practice. They may be of value in helping a couple choose an appropriate ART in a tertiary level service.
- A hysterosalpingogram may be used to test tubal patency. Laparoscopy is the gold standard test for tubo-peritoneal disease and is the preferred method, especially when evaluation of the pelvis is required. If there is a severe semen defect (score of 6, see next page) then there is no need for laparoscopy unless indicated for other gynaecological reasons (or following failed DI treatment). Furthermore for ovarian defects, a trial of therapy is indicated before laparoscopy is considered. Otherwise laparoscopy should be booked within 6 months in the following circumstances:

  1. severe cyclical pain or suspected pelvic pathology
  2. infertility of 18 months' duration and where there is a female history of any pelvic surgery, STDs or PID
  3. infertility of 18 months' duration and a female age ≥ 30 years of age
  4. otherwise unexplained infertility ≥ 3 years duration
  5. failed DI or ovulation induction (3-6 cycles of treatment)

Diagnostic Categories – to be completed at the secondary (specialist) level

The diagnostic model given here recognises the importance of the severity of a diagnosis and a combination of infertility factors on the probability of a successful outcome without treatment. To define the prognosis calculate the points for each diagnostic category 1, 2, 3, 4, 5 and 6.

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Patient ID: Complete patient details or place patient sticker here

Nat. Hospital No.: _____ Consultant: _____

Name: _____ D.O.B. ___/___/___

Address: _____

_____

Name of Assessor:

_____

Date of Assessment: ___/___/___

Initial Assessment

(1) Ovulation Defects	Categories	
From history, including • a plasma progesterone timed for 5-9 days before the next expected period. If cycle is long to be repeated at weekly intervals until next period • plasma FSH, LH, prolactin, thyroid function if the cycle is prolonged and/or irregular. FSH (day 2-5 cycle) for older women (is measure of biological age of ovary).	amenorrhoea - any cause	6
	oligomenorrhoea from any cause / luteal defect	3
	anovulation with normal menstrual cycle	2
	intermittent anovular cycles	1
	no ovulation defect	0
	SCORE 1	

(2) Semen Defects	Categories	
Semen sample collected after 2-3 days abstinence. To be repeated in 4-6 weeks if abnormal. The measurement of antisperm antibodies, post coital test or other sperm function tests are not essential for this category, but may be included as indicated	<1 million motile sperm/ml / severe ejaculatory dysfunction / severe sperm antibodies	6
	1 < 5 million motile sperm /ml / moderate antibodies / repeat negative PCT or sperm function abnormality	3
	5-10 million motile sperm/ml	2
	Any other semen defect	1
	No semen defect	0
	SCORE 2	

To be completed following laparoscopy

(3) Endometriosis	Categories	
The American Fertility Society Classification (American Society for Reproductive Medicine 1997). This requires direct visualization by laparoscopy. Surgical treatment at the time of diagnosis will be at the discretion of the gynaecologist conducting the procedure, depending on the common practice of the clinic.	stage IV AFS classification	6
	stage III AFS classification	3
	stage II AFS classification	2
	stage I AFS classification	1
	No endometriosis	0
	SCORE 3	

(4) Other Tubo-peritoneal Disease	Categories	
Although classification can be based on experience of examining specialist, we encourage the use of the American Fertility Society classification of adnexal adhesions (1988). In many cases the pathology may be different on each side. The adnexa with the least pathology should be used (best side). Surgical treatment at the time of diagnosis will be at the discretion of the gynaecologist conducting the procedure, depending on the common practice of the clinic.	Proximal or distal (complete or partial) occlusion on best-side / severe encapsulating tubal or ovarian adhesions on best-side, / missing tubes / or unsuccessful proximal or distal surgery after 12 months	6
	Moderate encapsulating tubal or ovarian adhesions on best-side adnexa / unsuccessful surgery after 6 months	3
	tubal polyps / mild encapsulating adhesions on best-side or / normal tube on best-side with tubal occlusion on the other-side or uterine adhesions	2
	minimal tubal or ovarian adhesions on best-side adnexa	1
	No tubo-peritoneal pathology	0
	SCORE 4	

(5) Other Factors	Categories	
These should be classified at discretion of specialist, e.g. psycho-sexual disorders fibroids intrauterine pathology	severe	6
	moderate	3
	mild	2
	minimal	1
	absent	0
	SCORE 5	

No diagnosis abnormality identified, i.e. unexpained infertility

(6) Unexplained Infertility	Categories	
If no diagnostic abnormality then define the duration of the unexplained infertility	Unexplained infertility ≥ 5 years	6
	Unexplained infertility ≥ 4 < 5 years	3
	Unexplained infertility ≥ 3 years < 4 years	2
	Unexplained infertility < 3 years	1
	SCORE 6	

Final Score for Diagnosis

Add scores 1,2,3,4,5,6 = Score D

SECTION 2

Access to Publicly Funded Treatment

A General Principles:

1. Provision of basic support and guidance at the primary level should be subject to normal primary care charging.
2. Simple ovulation induction may be managed by the GP in consultation with a specialist service.
3. Simple conditions requiring medical or psychological therapy should be provided within the primary or secondary services without need for access criteria.
4. Conditions with organic disease requiring surgery to enhance physical health (e.g. ovarian cysts, endometriosis) should be subject to the same criteria as for Gynaecology access criteria
5. Conditions that can be managed equally as well with ART or surgery (e.g. tubal occlusion) should be subject to access criteria for infertility. These treatments include AIH, IVF, IVF and ICSI, DI, ovulation induction using gonadotrophins (± AIH). The treatment available per individual couple should be directed by the specialist in charge of the individual / couples infertility and in consultation with that individual / couple. The cumulative amount of treatment available to people will depend on public funding available.

B Steps in defining access criteria:

1. Exclusion factors for access to treatment

The first is absolute - with access refused if there are situations that compromise the safety of the couple or a child. However, no factor may be used that is unlawful and that might breach the Human Rights Act or the Bill of Rights Act. Ultimately it will be the doctor, practicing at a primary, secondary or tertiary level, who will decide - and that doctor would need to defend this decision.

2. Modifying factors for access to treatment

These are conditions that can be modified to improve the chance of conception:

- Hydrosalpinges

  Complete distal tubal occlusion, or the hydrosalpinx, accumulates tubal fluid that may drain into the uterine cavity giving a detrimental effect on pregnancy rates with IVF. Depending on the severity of the tubal disease, either salpingostomy or salpingectomy should be performed in women planning entry into an IVF programme. The surgery should be performed by specialists trained in microsurgery or laparoscopic surgery. Each main centre in New Zealand has such specialists.

- Body weight

  Weight improvement programmes should be instituted before treatment is begun in women who are outside the BMI range of 28-32. Women with a BMI higher than 32 should be given a stand down period and classified as active review to see if they can achieve a lower BMI. There are factors that limit the success of weight improvement and, in this circumstance, it is reasonable to proceed with treatment provided the ovarian response is closely monitored. Treatment should continue only if the response is satisfactory.

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3. Calculation of the Priority Score

Each of the following criteria should be recorded following diagnosis and request for therapy and modified on an annual basis. For example, June 1 of each year may be regarded as the 'annual' date of revision, since new HFA funding rounds follow on July 1. Simple spreadsheet programmes are available that can recalculate a priority score simply by adding a new date. Copies of the programme are available from Wayne Gillett, Dept O&G, PO Box 913, Dunedin.

The final score is the product of a group of objective factors (O1–O4) and a group of social (subjective) factors (S1–S3). Points for each of the objective factors are directly proportional to the pregnancy rate. Points for the subjective factors were derived from the results of questionnaires returned by health professionals and consumers.

- The age of the female partner

The weighting of the points reflects the probability of conceiving with therapy.

- The prognosis of conceiving without treatment

See Section 1 for calculation of diagnostic scores.

If Score D = 6	then prognosis < 5% probability of conception in 1 year
If score D = 3 < 6	then prognosis 6-20 % probability of conception in 1 year
If Score D = 2 < 3	then prognosis 21-50% probability of conception in 1 year
If Score D < 2	then prognosis >50% probability of conception in 1 year

The weighting of these points reflects the inverse relationship of the likelihood of conceiving

- **The basal plasma FSH**

Ovarian reserve is commonly measured by basal FSH levels between days 2-5 of the menstrual cycle. The normal range will depend on the local assay. The weighting of points reflects the chance of conceiving. If donor oocytes are used in an IVF programme, the donor's FSH level should be measured. The best or lowest FSH in the last 6 months should be the figure used. An FSH in the range of 11-15 is a modifying factor and an FSH of greater than 15 is an exclusion factor.

- **A history of current smoking in female partner**

The points system reflects the relative risk on pregnancy outcome of smoking. Although this will become a priority factor we envisage that most women, by stopping smoking, will increase their priority points after 6 months and improve their eligibility depending on the threshold for access to treatment. We believe that every effort should be made by women seeking any form of fertility treatment to give up smoking. Note: the duration of the smoke-free period is to be 3 months with no cigarettes at all and with the male partner counselled as the effect of his smoking.

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- **Duration of infertility**

The points given here relate to how people feel about the burden of the duration of infertility, rather than how it affects the chance of pregnancy. The duration of infertility is to be cumulative of previous and current relationships. For single women or lesbians it will be on the basis of unexplained infertility to be confirmed by 12 cycles of DI of which 6 should be within an accredited RTAC unit.

- **Number of children**

This is defined as children currently living with the couple or person. Children living at home is defined as children under the age of 12 who have lived with the couple for most or all of the child's life. A child may include an adopted child.

- **Previous sterilisation**

Points given here recognise the burden of some people never having had children or the burden of having lost a child (children) by death.

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National Clinical Assessment Criteria (CPAC) for Treatment of Infertility

Patient ID: Complete patient details or place patient sticker here

Nat. Hospital No.: _____ Consultant: _____

Name: _____ D.O.B. ___/___/___

Address: _____

_____

Name of Assessor: _____

Date of Assessment: ___/___/___

Calculation of priority criteria points for publicly-funded infertility treatment

Criteria symbol	Points awarded	Criteria and their categories	Points available
O1		Chance of pregnancy without treatment	≤ 5% 10 6-20% 7 21-50% 4 >50% 2
O2		Woman's age	≤ 39 years 10 40-41 5 42+ 1
O3		Basal FSH, day 2-5 cycle, with respect to reference range	always within 10 sometimes above 8 mostly/always above 2
O4		Woman's smoking	non smoker 10 smoker 6
Multiply O1 x O2 x O3 x O4 = OC (points from objective criteria)			
=	OC	Now divide OC by 10000 = Revised OC (ROC)	ROC
S1		Duration of infertility	< 1 year 5 1<3 year 20 3<5 years 40 ≥ 5 years 50
S2		Number of children	None 30 1 by current relationship 10 > 1 by current relationship 5 ≥ 1 child by prev relationship 8
S3		Sterilisation reference range	neither partner sterilised 20 death of child 20 one partner sterilised 10
Sum S1 + S2 + S3 = SC (points from social criteria)		=	SC
Multiply ROC x SC = Priority Score (PS)		=	PS