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10 July 2012

Mr Jeff Dart
Coroners Registrar
Coroners Court of Victoria
Level 11, 222 Exhibition Street
MELBOURNE VIC 3000

Dear Mr Dart

Re: **Coroners Court of Victoria Reference number COR 2009 001537**

Thank you for your correspondence dated 21 May 2012 in relation to the death of Ms Selvamalar Murugathasan.

We have noted the coroner's recommendation and confirm Monash IVF is in agreement with the principles underpinning the recommendation.

The Monash IVF Clinical Guidelines Manual (September 2011 update), includes a section specifying arrangements for managing patients with high risk medical conditions (refer to Attachment 1 for an extract of the entire chapter of the Manual). With respect to patients receiving anticoagulation therapy, the Monash IVF Clinical Guidelines Manual recommends the following:

"Pre registration evaluation and management planning by the (treating) clinician

- **The (treating) clinician identifies the potential high-risk patient, obtains a full medical history and list of specialists involved in her ongoing care.**
- Optimisation of health pre-conception: The patient should be given an account of the potential difficulties in Assisted Reproductive Technology (ART) and pregnancy relevant to her own situation.
- Improved prospects of a healthy pregnancy and child through improving her health prior to ART should be highlighted; this discussion should be well documented, including covering adverse events.
- **A management plan should be developed and forwarded, along with a summary of the medical issues of concern to Monash IVF for inclusion in the patient's history."**

I note all accredited Monash IVF specialists are required to adhere to the Monash IVF Clinical Guidelines in the management of patients undergoing fertility treatment.

Thank you for the opportunity to provide input on this matter.

Yours sincerely

James Thiedeman
Chief Executive Officer
Monash IVF

14. COMPLEX AND DIFFICULT PATIENTS

14.1 Review of Patients with Poor Outcomes

Poor outcomes include the failure to achieve ongoing pregnancy despite the transfer of embryos AND/OR the failure to respond adequately (in terms of number/quality of eggs) to stimulation.

Histories of such patients are to be reviewed regularly at clinical meetings.

Patients may be referred for review at the discretion of the clinician or Monash IVF staff member (after prior consultation with the patient's clinician) to the site or clinical director who may choose to involve the Medical Advisory Committee (MAC) in seeking further guidance.

i. Poor Responders to Ovarian Stimulation

Poor response to gonadotropins is associated with chronological aging, and is reflected by decreasing pregnancy rates with advanced age. This is also clearly demonstrated in other treatments of sub-fertility (e.g. DI) as well as natural conception. However, there is not a strict correlation with age and some women demonstrate poor responsiveness at a relatively young age.

It is likely that poor response to gonadotropins in IVF precedes any endocrine changes. This reproductive aging is manifest by decreased response to FSH stimulation, fewer and poorer quality oocytes recovered, and lower fertilization and implantation rates. The accepted parameters of ovarian responsiveness (antral follicle count and early-follicular FSH levels) are not always reliable.

Poor response to FSH stimulation is very resistant to therapeutic interventions.

DEFINITION: Cycle cancellation due to failure to develop 3 or more follicles or a failure to collect at least 3 mature eggs at either of a minimum of 2 (two) using standard stimulation protocols (described in Section 3) at a dose 450 IU FSH.

It is recognised that this definition will include both women at younger age with apparently normal ovarian reserve AND more often in older women.

- The following should be noted:
  - There is **no evidence** that increasing the FSH dose during the follicular phase is of any benefit. Commencing the next cycle on a higher dose seems logical, but studies have not been able to demonstrate its beneficial effect. **The maximum dose of FSH remains 450 IU per day.**
  - Changing from Pill down-regulation to BOOST, by reducing the amount of GnRH agonist, decreases suppression of the pituitary may theoretically improve response by reducing suppression of endogenous gonadotrophins. However, recent evidence shows his does not improve outcome.
  - Cessation of GnRH agonist in follicular phase. The theory behind this regimen is as for above, but evidence is again lacking
  - Combined clomiphene and FSH. Whilst this was a popular protocol for COH in the 1980's there is no evidence that the regime will improve the outcome in poor responders.
  - Recombinant LH: There is no evidence for its efficacy in poor responders.

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ii. Systematic Evaluation New Options of Management Options for Poor Outcome Patients (Both Repeated IVF Failure and Poor Responders)

At any one time, Monash IVF will undertake a systematic examination of one new option for poor responders. This makes it essential that the definition is agreed and strictly adhered to.

This examination of new approaches will take the form of:

- **A pilot study** using minor innovations of currently used approaches or that emerging and supported by at least one publication with level 1B/2A evidence in a reputable peer-reviewed publication.
- **Research protocols** that will require similar development but will include review by the Research Committee and formal HREC approval. Such trials **must** be performed with a view to peer review publication and be rigorously designed including statistical power.

All these developments MUST undergo the processes of presentation and agreement in principle, subsequent evaluation by the MAC for detailed scientific/clinical assessments and organisational impact, followed by formal ratification prior to implementation.

14.2 Managing High Risk Mental Health Patients

This group of patients present challenges in counselling, obtainment of informed consent, monitoring and handling of adverse outcomes. As such, Monash IVF requires special attention be paid to evaluation of potential patients. The following is the recommended management pathway.

i. Initial Assessment by Clinician

It is the responsibility of the treating clinician to identify and refer for assessment potentially difficult patients, such as those with a history of -

- **Past or current serious psychiatric history**
  - **Any history of substance or alcohol abuse**

It is recommended that an assessment in potentially difficult cases involve an independent psychiatric or psychological assessment.

ii. Case Management Meeting BEFORE Referral to Monash IVF

A case management meeting is scheduled between the referring clinician, the Clinician's nurse coordinator and the manager of counselling department to review the case and potential implications of treating the patient. The Clinician may, at their discretion, wish to involve the Medical Director. To respect the patient's confidentiality the case can be de-identified.

iii. Referral to the Independent External Psychiatrist for Assessment of Mental Health Status

If the patient is identified as high-risk (i.e. they suffer from a psychiatric illness, has had recent admissions to hospital, or a history of suicide attempts or self harm behaviour) and is likely to have special needs regarding their medical and psychological care, they will be referred to either an independent psychiatrist to assess their current mental health status to identify what additional treatment care they may require or whether it is indeed appropriate to treat the patient. Or in Victoria, the clinic may refer the case to PRP. *(See state specific details as follows)*

Victoria

Independent Psychiatrist –

Dr John King
1 Murray St
Clayton Vic 3168
☎ 9562 9695

(Dr King also consults at the Melbourne Clinic in Richmond.)

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DHS Patient Review Panel (PRP) as of July 1 2009

As of July 1 2009 a Patient Review Panel (PRP) overseen by DHS will accept referrals from clinics when the clinic has concerns about treating people due to complex mental health conditions or where there may be concerns about a person's ability to; a) give informed consent and; b) be of mental and physical fitness to cope with treatment and parent a child. These cases may be referred to the PRP for independent assessment and review. A decision to treat or not treat the patient may be passed down by the PRP. The patient may wish to appeal this decision. An appeals process can be arranged through VCAT.

Queensland
Refer to Site Medical/Clinical Director

ACT
Refer to Site Medical/Clinical Director

iv. Follow-up Case Management Meeting

Where cases are reviewed in-house by the clinic, the clinician should schedule a meeting with the manager of counselling department and seek input, at their discretion, from the Site Clinical Director. This meeting will review psychiatric report and identify:

- Whether patient should receive treatment, and;
- If treatment is to be offered admission on the IVF program then a treatment plan will be developed to take into consideration the patients special needs.

v. Patient then Referred to Monash IVF

Once it has been established that the patient can be treated and their special needs can be met, the patient is then referred into the Monash IVF system for registration onto the IVF program, screening tests, mandatory counselling.

vi. Meeting BEFORE Treatment Commences with Patient, Doctor, Site Clinical Director and Monash IVF Counsellor

Once it has been determined that the patient can be treated and their special needs catered for, a meeting will be set up with the patient before treatment commences to discuss their treatment plan. Example outlined below -

- Meeting with patient to discuss medical treatment plan and psychological care plan.
- Liaison between doctor, Monash IVF counsellor and independent mental health specialist to develop care management plan for patient.
- Patient to see independent psychiatrist and / or psychologist for weekly visits whilst on IVF program.
- Follow-up care plan to address special psychological needs if treatment unsuccessful. This is to manage the patient's expectations and to take into consideration any specific mental health needs, such as admission to psychiatric unit.

vii. Case Management Once Patient Is Registered With Monash IVF

If mental health issues are picked up by either a counsellor or nurse when the patient is already registered with Monash IVF, the case needs to be referred to the Manager of Counselling, the Medical Director and the Operations Manager for review. Depending on the severity of the mental health condition the recommendations may be made to:

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a) Refer to the PRP (Victoria specific)
b) Implement specific psychological interventions whilst the patient continues with their IVF treatment.
c) IVF treatment may be temporarily suspended and patient requested to undergo psychiatric care until mental health condition has stabilised.
d) To determine whether condition has stabilised a report from the treating psychiatrist will be required.

14.3 Managing Other Complex and Difficult Patients

Clinicians need to identify patients who they feel have the potential to experience or create difficulties during ART treatment and to be 'organizationally challenging' through making demands outside the norm.

Victoria

From July 1 2009 Monash IVF may elect to refer this category of patient to the PRP for assessment of the patient's eligibility to proceed with ART.

Queensland

Refer to Site Medical/Clinical Director

ACT

Refer to Site Medical/Clinical Director

At risk groups may include those who have;

- Had large numbers of previous ART attempts.
- Been through multiple different ART programs.
- Seems aggressive or excessively demanding.
- An unusually high level of concerns in any area
- Any complex psycho-social situation.

In this event, it is recommended that the following course of action be taken.

i. Case Management Meeting

A plan of management will be drawn up highlighting the areas that require specialist attention and informing specific staff members.

ii. Communication with Difficult or Vexatious Patients

The Clinician will discuss the relevant issues with Monash IVF staff and ensure that the Operations Manager is aware such that these events are 'captured' and can be evaluated to improve future service.

After full discussion, direct contact with the patients will be made by an agreed individual (clinician or otherwise) such that the message is clear and consistent.

14.4 Newly Separated Women Wanting to do IVF

Certain women who have relationship difficulties and who present with ambiguity and vacillation about whether to undergo treatment as a single woman or with a partner present difficulties from a counselling perspective. NHMRC Guidelines and ANZICA Guidelines require that there is a duty of care not only to the woman / couple undergoing treatment but also that the well-being and welfare of the unborn child be considered. This kind of situation presents complexities that require additional counselling and support.

If these women proceed with IVF treatment under such circumstances the risks could include:

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i. Psychological distress for both woman and / or partner -

- Not enough time to resolve issues in relationship.
- If woman becomes pregnant with donor sperm and then reunites with former partner, implications for male partner in accepting child.
- The woman may not be in a fit state to make decisions that are life changing and have implications for her and the unborn child.
- The male partner and the known donor also have the right to make informed decisions about the consequences that may occur if proceeding with treatment under such circumstances.
- Erratic behaviour could signal undiagnosed mental health condition.

ii. Environmental instability for woman -

- Woman's life may be in physical and emotional upheaval, living in temporary accommodation, still in process of separating finances and dealing with property settlements and grieving loss of relationship.
- Is she in a position to care for herself and a new born child?
- Poor or non-existent support networks.

To reduce the risks associated with such complex situations the Counselling Department recommends:

- A case management meeting with the treating IVF clinician.
- A cooling off period of 3-6 months (minimum 3 months).
- Counselling for all relevant parties.
- The woman seeking treatment provides evidence of the legal status of the relationship and that the relationship has in fact ended.
- That independent psychological assessment is considered for the woman (and if required the partner) who presents with frequent changes of different partners or who vacillates between reuniting with partner and breaking up on a regular basis. This behaviour should alert the clinic to the risk of emotional and psychological instability of the woman and the situation.
- Where a woman seeking treatment wishes to use her former partner as a known sperm donor, further counselling in addition to the statutory donor counselling requirement is recommended to address the additional complexities of their past relationship and their future relationship.
- Known sperm donors are subject to a six month quarantine period, including the husband.
- Freezing sperm at the start of the quarantine period is not a guarantee that the sperm can be used.

14.5 Managing Patients with High Risk Medical Conditions

Patient's with high risk medical conditions present challenges in counselling, informed consent, management planning, treatment and in the handling of adverse outcomes. Monash IVF requires special attention be paid to evaluation of these patients.

i. Female patients

Significant medical co-morbidities may present a threat to the safe performance of ART, to the health of the mother during pregnancy and to the health of their offspring. A detailed consideration of patient's eligibility to undergo ART must be undertaken before registration at Monash IVF.

An evaluation of safety during pregnancy and the development of a management process for women with medical illness, such as renal insufficiency, hypertension or diabetes, are an essential part of clinical practice, and frequently involves both the GP and other specialists.

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A particular concern in ART, and the focus of these guidelines, is increasing problem of severe obesity (BMI>40) and the prevalence of diabetes, vascular disease and thromboembolic disorders in this population. These women are also at risk of respiratory difficulties and anaesthetic risks.

The following is the recommended:

Pre registration evaluation and management planning by the clinician

- The clinician identifies the potential high-risk patient, obtains a full medical history and list of specialists involved in her ongoing care.
- Optimisation of health pre-conception: The patient should be given an account of the potential difficulties in ART and pregnancy as relevant to her own situation.
- Improved prospects of a healthy pregnancy and child through improving her health prior to ART should be highlighted; this discussion should be well documented, including covering adverse events.
- A management plan should be developed and forwarded, along with a summary of the medical issues of concern to Monash IVF for inclusion in the patient's history.

Approach to the obese female patient

This evaluation and care plan is recommended for women with a BMI > 40 kg/m^2 and/or those with significant co-morbidities of the metabolic syndrome:

1. Full medical evaluation

Referral to a physician is strongly recommended with evaluation for diabetes (fasting blood glucose or glucose tolerance test), cardiorespiratory disease and thrombo-embolic risk

2. Explanation of the risks of obesity for ART, pregnancy and birth outcomes

These should highlight;

- the anaesthetic risks associated with morbid obesity
- risk of pregnancy; including miscarriage, pre-eclampsia, gestational diabetes, labour difficulties
- peri-natal difficulties experienced by offspring of obese/diabetic mothers
- data on congenital anomalies and long term health.

Some clinicians may prefer to refer to an **obstetrician experienced in high risk pregnancy** to pre-conception evaluation.

3. Referral to a dietician and lifestyle review:

This should involve the local doctor and allied health staff. A realistic weight loss target and time frame should be set to achieve the BMI < 40. This management plan must take into account patient specific issues such as age, medical history, and reproductive circumstances.

4. Failure to achieve weight loss target

In the event that these targets are not met and the clinician believes that ART treatment should nonetheless be offered, then the following steps are MANDATORY prior to registration

- **Modified consenting and management process:** The patient is informed that they are not suitable for routine ART care and that special conditions and consenting processes apply.
- **An anaesthetic opinion** must be sought regarding the safety of sedation at EPU. This may require consideration of additional staff and facilities. Any additional costs will need to be explained and borne by the patient.

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If the anaesthetic can be administered with a risk that is acceptable to both patient and medical staff, then registration can proceed with;

- Provision to Monash IVF of all medical details & opinions from relevant specialists
- **Modified consent form** will highlight
  - the generic risks of obesity
  - any patient specific additional risk for adverse events.

On morning of EPU, the 'doctor of the day' must review arrangements with the anaesthetist

5. Exclusion from treatment

The following thresholds have been established that preclude treatment at Monash IVF regardless on the above considerations and opinion re risk/benefit –

1. patient condition deemed incompatible with a healthy pregnancy
2. refusal by the anaesthetists to treat
3. patient's refusal to comply with these guidelines

6. Local service practitioner recommendations -

Victoria

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Dr Carolyn Allan
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Honorary Senior Lecturer
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Queensland

Unique Healthy Lifestyles for Fertility Program
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Allamanda Medical Centre
Suite 1, 25 Spendelove Street
Southport QLD 4215
T: (07) 5519 1600

ACT

Please refer to the Site Medical Director.

ii. Male Patients

Concomitant medical problems for male patients may present anaesthetic or bleeding risks for testis biopsy.

The requirements for female patients as per the above guidelines, also applies to grossly obese men or those with other potential anaesthetic risk (such as prior coronary heart disease) in whom a general anaesthesia might be needed for TESE etc.

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