Annex I

Supplementary Code of Practice on Reproductive Technology - Artificial Insemination by Husband (AIH)

Council on Human Reproductive Technology

SUPPLEMENTARY CODE OF PRACTICE ON REPRODUCTIVE TECHNOLOGY - ARTIFICIAL INSEMINATION BY HUSBAND (AIH)

Contents | | Page

I.	Introduction	i
	• *Preamble* • *Application of the Supplementary Code* • *Interpretation of the Human Reproductive Technology Ordinance and Promulgation of the Supplementary Code*	
II.	Procedure of Artificial Insemination by Husband (AIH)	ii
	• *Classification of AIH*	
III.	Staff	ii
	• *General* • *Person Responsible* • *Licensee* • *Medical Practitioners* • *Nursing Staff/Healthcare Assistants* • *Counsellors* • *Fitness to Practise*	
IV.	Facilities and Equipment	iv
V.	Assessment of Clients	iv
VI.	Information to Clients	iv
VII.	Consent	v
VIII.	Counselling	v
	• *General* • *Counselling for Potential Clients of AIH Service*	
IX.	Treatment Method	vi
X.	Screening and Selection of Sperm	vi

XI. Record Keeping and Information Management vii

- *Accuracy and Confidentiality of Information*
- *Keeping of Record*
- *Submission of Information to Council*
- *Handling of Personal Data under the Personal Data (Privacy) Ordinance*
- *Disclosure of Personal Information*

XII. Handling of Complaints viii

- *Complaints against RT Centres*
- *Breach of the Supplementary Code*

XIII. References ix

SUPPLEMENTARY CODE OF PRACTICE ON REPRODUCTIVE TECHNOLOGY - ARTIFICIAL INSEMINATION BY HUSBAND (AIH)

I. Introduction

Preamble

1.1 Since artificial insemination by husband (AIH) is regarded as a relatively simple RT procedure, the Council considers that a simpler code is sufficient for AIH procedures. This Supplementary Code of Practice on Reproductive Technology - Artificial Insemination by Husband (AIH) (the Supplementary Code) is prepared for compliance when AIH is performed by a RT service provider (whether or not other RT procedures are provided by the same service provider). However, when RT procedures other than AIH are performed by the RT service provider, he should also comply with the provisions of the Code of Practice on Reproductive Technology and Embryo Research (the Code) in relation to the other RT procedures.

1.2 This Supplementary Code provides guidance for good practice, as described in subsequent paragraphs, which aim to support proper clinical and scientific procedures, to safeguard the health and interests of service users and to protect the welfare of children born through AIH. Professionals concerned should still follow the codes of practice and professional ethics of their individual disciplines. This Supplementary Code is not meant to supersede these.

Application of the Supplementary Code

1.3 The Supplementary Code is annexed to the Code and forms part and parcel thereof. The Code came into effect on 1st August 2007.[1] It will be reviewed and updated as necessary to keep up with developments in RT.[2] The Council, which is the licensing authority for RT services and embryo research, shall take into account any observance of or failure to observe the provisions of the Supplementary Code when considering granting, renewal, variation, revocation or suspension of licences relating to the practice of AIH.[3]

Interpretation of the Human Reproductive Technology Ordinance and Promulgation of the Supplementary Code

1.4 All personnel involved in the provision of AIH procedure are advised to familiarize themselves with the Human Reproductive Technology Ordinance (the Ordinance). Reference should be made to the Ordinance for definitions of specific terms.

1.5 The Supplementary Code must be construed in a manner consistent with the provisions of the Ordinance.

[1] s.8(6) of the Human Reproductive Technology Ordinance (the Ordinance)
[2] s.8(3) of the Ordinance
[3] s.9 of the Ordinance

II. Procedure of Artificial Insemination by Husband (AIH)

2.1 In this Supplementary Code, AIH refers to the placement of the husband's sperm into the vagina or uterus of his wife otherwise than by sexual intercourse. Sperm washing may be performed before the husband's sperm is used for this purpose. Ovarian stimulation may be used with appropriate monitoring. Every care should be made to minimize the risk of multiple pregnancies and reference should be made to the Hong Kong College of Obstetricians and Gynaecologists Guidelines Number 1.

Classification of AIH

2.2 The Council considers it appropriate to broadly categorize AIH into three types, namely **intravaginal, intracervical** and **intrauterine** insemination. Intravaginal insemination refers to the placement of sperm into the vagina. Intracervical insemination refers to the placement of sperm at the cervical os. Intrauterine insemination refers to the placement of sperm (usually after processing) into the uterine cavity. Respective guidelines for the three types of AIH are shown in the ensuing paragraphs.

III. Staff

General

3.1 As required by the Ordinance, no person shall carry on RT activities except pursuant to a licence.[4]

Person Responsible

3.2 The "person responsible", in relation to a licence, refers to the individual specified in the licence as the individual under whose supervision the activities authorized by the licence shall be carried on.[5]

3.3 It shall be the duty of the person responsible to ensure that -[6]

(a) the other persons to whom the licence applies[7] are of such character, and are so qualified by training and experience, as to be suitable persons to participate in the relevant activity authorized by the licence (For persons responsible of reproductive technology centres with satellite centres/ associated doctors, the requirement as stipulated in para. 2.3(a) of the main code should also be followed.);

(b) proper equipment is used;

[4] s.13 of the Ordinance
[5] s.2(1) of the Ordinance - interpretation of the term "person responsible"
[6] s.24(1) of the Ordinance
[7] s.24(3) of the Ordinance

(c) proper arrangements are made for the keeping of semen/sperm and for the disposal of semen/sperm that have been allowed to perish;
(d) proper practices are used in the course of that activity; and
(e) the conditions of the licence are complied with.

3.4 The person responsible should ensure that this Supplementary Code is made known to all staff involved.

Licensee

3.5 The "licensee", in relation to a licence, is the holder of the licence as defined in the Ordinance.[8]

3.6 It is the duty of the licensee to ensure that the person responsible discharges his/her duty. The discharge of the duty by the person responsible should not be prejudiced if the licensee and the person responsible are the same person.[9]

Medical Practitioners

3.7 Artificial insemination should be administered or supervised by a registered medical practitioner. Subject to this paragraph and para. 3.9 below, intrauterine insemination should be performed by a registered medical practitioner recognised as an accredited specialist in Obstetrics & Gynaecology or Reproductive Medicine under the Specialist Register of the Medical Council of Hong Kong. Medical practitioners in training may also carry out intrauterine insemination procedure under supervision of such specialists.

3.8 When ovarian stimulation with gonadotrophin is used for any of the three insemination procedures, it should be done or supervised by a specialist in Obstetrics & Gynaecology or Reproductive Medicine.

Nursing Staff/Healthcare Assistants

3.9 Nursing staff employed by RT centres[10] should be registered nurses or enrolled nurses under the Nurses Registration Ordinance (Cap. 164) and be appropriately trained for the duties they carry out. Nursing staff with appropriate training may also perform intrauterine insemination procedures under the supervision of a specialist who possesses the qualifications set out in para. 3.7 above. Other healthcare assistants should work under the supervision of the medical practitioner and be appropriately trained for the duties they carry out.

Counsellors

3.10 Counselling may be provided by doctors, nurses, social workers, clinical psychologists or other persons with suitable experience and/or qualifications as appropriate.

[8] s.2(1) of the Ordinance - interpretation of the term "licensee"
[9] s.23(3) and s.24(2) of the Ordinance
[10] RT centres refer to the hospitals or centres or clinics providing AIH services

Fitness to Practise

3.11 In the case of medical practitioners, reference should also be made to the Code of Professional Conduct for the Guidance of Registered Medical Practitioners laid down by the Medical Council of Hong Kong on fitness to practise.

IV. Facilities and Equipment

4.1 The person responsible must ensure that proper facilities and equipment are used and maintained.[11] Hormonal assay facilities should be available if needed.

4.2 The minimum facilities and equipment required for RT centres offering intrauterine insemination service should include-

(a) ultrasound equipment, which should be readily available in the RT centre for monitoring ovarian stimulation; and
(b) sperm washing facilities, which should be readily available either at the RT centre itself or at another laboratory which is licensed for the purpose and which is able to provide the required service in a timely manner.

4.3 If counselling is carried out in the RT centre, it should be provided in a place with privacy and comfort where discussion can take place undisturbed.

V. Assessment of Clients

5.1 In accordance with the Ordinance, AIH procedures should only be provided to persons who are the parties to a marriage[12].

5.2 The clients concerned should be offered fair and unprejudiced assessment. Clients' medical conditions should be fully assessed to determine the most appropriate treatment option.

VI. Information to Clients

6.1 RT centres should devise a mechanism to ensure that relevant information is given to persons seeking AIH treatment. RT centres should provide clients with information on the services offered.

[11] s.24(1)(b) of the Ordinance

[12] The term "parties to a marriage" has not been defined under the Human Reproductive Technology Ordinance. For his/her own protection, if a service provider is asked to provide RT services to a couple married outside Hong Kong, he/she should ensure that the marriage was celebrated or contracted in accordance with the law in force at the time and in the place where the marriage was performed and recognized by such law as involving the voluntary union for life of one man and one woman to the exclusion of all others. Please refer, in this regard, to the definition of "monogamous marriage" under section 2 of the Matrimonial Causes Ordinance (Cap. 179).

6.2 Persons seeking AIH treatment should be informed of the following -

(a) explanation of the procedure;
(b) possible discomfort, side effects and complications of treatment to the woman and the resulting pregnancy including, where relevant, risk of ovarian hyperstimulation syndrome or multiple pregnancies and indications for embryonic/fetal reduction;
(c) limitations and possible outcomes of the treatment;
(d) any other options available; and
(e) charges for services.

VII. Consent

7.1 Informed consent with respect to receiving AIH treatment must be obtained in writing. Such consent must be obtained before commencement of any active treatment procedures for each cycle of treatment, but not earlier than 6 months prior to the AIH treatment.

7.2 RT centres are required to make use of the sample Consent Form (14) at **Annex II** of the Code unless there are justifiable reasons why they should not be used or should be departed from or modified.

VIII. Counselling

General

8.1 The clients concerned should be provided with counselling by doctors, nurses, social workers, clinical psychologists or other persons with suitable experience and/or qualifications as appropriate.

8.2 Non-directional counselling on the implications of the AIH procedure and consideration of other options must be offered to clients before they consent to AIH procedure. Couples seeking treatment should be given adequate time to consider the issue.

8.3 Information obtained during counselling must be kept in confidence.

8.4 Proper records should be kept of the counselling service offered and provided.

Counselling for Potential Clients of AIH Service

8.5 Counsellors should ask potential clients to consider carefully all possible implications before receiving AIH service especially when ovarian stimulation has to be done, such as -

(a) the financial implications of the AIH treatment (e.g. there is the possibility of multiple pregnancies);

(b) their feelings about manipulation of the husband's sperm outside his body, and the possible storage and disposal of the sperm;
(c) the chances that treatment may fail;
(d) the possibility of the need of embryonic/fetal reduction;
(e) the alternative of adoption of a child;
(f) the possibilities that the implications of and feelings about their AIH treatment may change as personal circumstance changes; and
(g) all the terms and conditions set out in the consent form.

IX. Treatment Method

9.1 The attending clinician must ensure that the treatment method offered is the one which best suits the couple's particular medical indication.

9.2 Established clinical practices and laboratory standards should be adopted to safeguard the health and safety of clients.

9.3 The indication for selecting the AIH procedure must be stated in each case.

9.4 Side effects and complications arising from the AIH procedure must be recorded for each case.

9.5 When ovarian stimulation has to be carried out, RT practitioners must take measures to prevent high multiple pregnancies whenever possible. This is to avoid the known risks of fetal mortality and morbidity in such cases, the health hazards to the mother and the possible psychological and practical consequences for both parents.

9.6 If a pregnancy involving multiple fetuses should occur despite the above-mentioned precautions having been taken, and if the prognosis for the fetuses is so unfavourable, a procedure of fetal reduction may be necessary. The carrying out of fetal reduction procedure should comply with section 47A of the Offences Against the Person Ordinance (Cap. 212). The possibility of embryonic/fetal reduction should be included in the pre-treatment counselling. Parents should be clearly informed of the reasons for embryonic/fetal reduction and the possible risks involved, and the procedure may not be carried out without their consent.

9.7 Embryonic/fetal reduction should not be carried out simply to comply with the request of the parents who prefer to have a fewer number of children from the pregnancy.

X. Screening and Selection of Sperm

10.1 For AIH, both cryopreserved and fresh semen/sperm of the husband can be used. If RT centres store semen/sperm for their clients, a proper and safe storage facility must be provided to preserve the viability of semen/sperm and to minimize the chance of accident, loss or contamination. In the case that the semen/sperm is stored at a RT centre and is transferred to another RT centre where AIH is to be performed, the

guidelines as contained in **Appendix IV** regarding the local transfer of stored gametes between RT centres should be observed.

10.2 Semen/sperm which has been subject to procedures carrying an actual or unreasonable risk or harm to its developmental potential should not be used for treatment.

10.3 Intrauterine insemination should be carried out or supervised by an obstetrician or gynaecologist or a specialist in reproductive medicine, or by registered medical practitioners under training or nursing staff with appropriate training, and under supervision of the specialist as mentioned above. Sperm washing should also be performed as part and parcel of the procedure, and should be carried out either at the RT centre itself by a person who has undergone the appropriate training, or at another laboratory licensed for the purpose.

10.4 If the semen is cryopreserved for storage, appropriate measures should be taken to minimize the risk of contamination of the semen stored.

XI. Record Keeping and Information Management

Accuracy and Confidentiality of Information

11.1 RT centres must ensure that personal records with identifying information are kept in confidence with controlled access and disclosure of such should be in circumstances permitted by the Ordinance.[13]

Keeping of Record

11.2 RT centres must keep medical records containing the names, correspondence addresses, identity card/passport numbers of all patients. The record should include information on the AIH procedure performed and outcomes of the procedure as far as it is practicable. The registers, namely Patients Register and Children Register, and records required to be kept and maintained by RT centres are listed at **Appendix IX**.

11.3 General medical record kept and maintained under an AIH licence should be retained by the RT centres for at least 6 years after the patient ceases to be a client of the RT centre.

Submission of Information to Council

11.4 RT centres are required to submit to the Council non-identifying information on AIH treatments provided to clients on a quarterly basis. The information required should be submitted in the prescribed format using the DC Forms 4 and 7 at **Annex III**.

---

[13] s.34, s.35 and s.36 of the Ordinance

11.5 Other non-identifying data in the prescribed format, i.e. annual statistics form (AS Form) 7 at **Annex IV**, should be submitted on an annual basis to the Council by end of March every year. The use of uniform definitions should be adopted (please refer to the glossary of abbreviations and common terms used in RT and the explanatory notes for completing the forms on annual statistics on RT treatment in the Code).

Handling of Personal Data under the Personal Data (Privacy) Ordinance

11.6 The Personal Data (Privacy) Ordinance (Cap. 486) enables individuals to request access to and correction of personal data held by data users. RT service providers are advised that the rules and principles stipulated in the Personal Data (Privacy) Ordinance on the collection, retention, use, disposal, access to and correction of the personal data should be complied with.

Disclosure of Personal Information

11.7 RT centre should clearly explain to the patients and their spouses that the personal data they provide in connection with the provision of RT procedure(s) may be disclosed for the purposes as stipulated by the Ordinance and the Code published from time to time by the Council. Consent Form (14) (please note also para. 7.2 above) contains provisions drawing clients' attention to such disclosures by reference to **Appendix XI** of this Code. RT centres should ensure that clients understand and consent to such disclosures.

11.8 If a RT centre engages the service of another laboratory licensed by the Council for the purpose to carry out sperm washing procedure for a client, a copy of the consent form (14) duly signed by the client must be provided to the laboratory.

11.9 The laboratory whose service is engaged as mentioned in para. 11.8 above must in turn comply with all requirements in relation to the confidentiality, access and disclosure of the personal information, information and records of the client as stipulated by the Ordinance and this Code.

XII. Handling of Complaints

Complaints against RT Centres

12.1 RT centres should have in place an administrative arrangement with a designated staff at the appropriate level to acknowledge receipt of complaints and to take charge of investigations. The outcome of the investigation should be recorded and explained to the complainant.

12.2 If the complainant is dissatisfied with the outcome of investigation by the RT centre, he/she should be advised about other avenues of complaint including, if appropriate, the Investigation Committee of the Council or the Medical Council of Hong Kong (for matters relating to possible professional misconduct of medical practitioners) or other regulatory professional bodies in Hong Kong.

Breach of the Supplementary Code

12.3 Any complaints of breach of the Supplementary Code will be investigated by the Investigation Committee of the Council.[14] Failure to co-operate with the Investigation Committee will be taken into account by the Council in assessing whether there is a ground for revocation, variation and/or suspension of licence.

12.4 Professionals concerned are reminded that they are also under codes of practice or ethics of their respective professional disciplines.

XIII. References

13.1 In interpreting the terms used in the Supplementary Code, reference should be made to the glossary of abbreviations and common terms used in RT and the explanatory notes for completing the forms on annual statistics on RT treatment in the Code.

[14] Schedule 1 s.6(c) of the Ordinance