Comments of the Hong Kong Bar Association

Consultation on the Proposed Principles of Amendments to Code of Practice on Reproductive Technology & Embryo Research

The following are the comments of the Hong Kong Bar Association on the proposed "principles of amendments" to the Code of Practice on Reproductive Technology and Embryo Research (the **Code**).

Introduction and Background

1. The Council on Human Reproductive Technology (the **Council**) was established under the Human Reproductive Technology Ordinance (Cap. 561) (the **Ordinance**) in April 2001.

2. Under section 8 of the Ordinance, the Code has been produced, first coming into effect on 1st August 2007.

3. In 2011, the Hong Kong Bar Association reviewed a draft revised Code, followed by a further review of another version of the Code in 2023. The current version of the Code became effective on 1 January 2024.

4. We understand that, based on feedback provided by stakeholders during the consultation of the last review of the Code in 2023, the Council is basically agreed that the duration and age limits on storage of gametes (including both sperms and eggs) or embryos "*for own use*" would be lifted on the basis that such limits should be a medical instead of a legal issue (the **Proposal**).

5. We further understand that the Council is considering modifying the legislative framework (i.e. the Ordinance, and the Regulation and Code thereunder) to facilitate the implementation of the Proposal; and that insofar as the Code is concerned, the Council proposes a number of "*principles of amendments*" (collectively, the **Proposed Principles**):

a. **Proposed Principle 1:** During counselling, patients should be provided with up-to-date scientific information that are applicable to specific types of gametes or embryos, such as the risks of egg retrieval procedures, the rapid decline in fertility/pregnancy rate associated with aging of women, the risks of advanced maternal age and the social impacts of delayed childbearing. Patients must sign a consent form to acknowledge the receipt of such information. The counselling records should be properly documented for review by the Council when required.

b. **Proposed Principle 2:** Additional counselling and written consent after five years of initial storage, and for every two years afterwards, are required.

c. **Proposed Principle 3:** More detailed data on storage of gametes or embryos for own use such as marital status, age distribution (including age of storage and usage) and type of identity document of patients would be collected through annual statistics to be submitted by licensed centers for regulatory purposes.

HKBA's Comments

The Proposal in General

6. As regards the Proposal that the duration and age limits on storage of gametes or embryos for own use should be handled as a medical issue instead of a legal issue, and that the corresponding legal restrictions be lifted, the HKBA's general comment is that it may be useful for the phrase "*for own use*" to be clearly defined.

7. In this regard, we note that the phrase "*for own use*" is referred to in sections 10.7, 10.11 (d)(f)(g) and 10.15, and Consent Form 2 and the Index of Annexes of the Code. However, the phrase is not defined within these sections or in the Code. A clear definition is crucial to ensure that all stakeholders understand the parameters of storage limits and the associated legal and medical responsibilities.

8. Further, and more fundamentally, the Proposal's working assumption is that the duration and age limits of gametes and embryos "*not for own use*" should be managed differently than those intended "*for own use*".

9. It may provide more clarity to spell out the reason behind the validity of the working assumption. It may be argued that the same considerations behind the need for counselling as to the storage of gametes and embryos would equally apply to those "*not for own use*". It may be useful to think through the distinction and whether or not counselling should also be required for gametes and embryos which are stored but "*not for own use*"; which in turn may affect the relevant changes to be made to the Code.

Re the Proposed Principles

10. As for **Proposed Principle 1**, while it is appreciated that such aims to enhance patient awareness through counselling and facilitate informed consent in decision-making, there are two points to be made.

11. The proposed principle that patients should be provided with a list of up-to-date scientific information raises a critical concern similar to the challenges associated with the concept of informed consent.

12. Informed consent implies that patients are fully aware of and understand the risks and benefits associated with a medical procedure.

13. However, in the rapidly evolving landscape of reproductive technology, it is increasingly difficult to remain legally abreast of all scientific advancements and the statistical analyses of data.

14. This challenge is exacerbated by the advent of artificial intelligence and precision medicine, which continue to transform our understanding of reproductive health.

15. Moreover, it is essential to recognise that the significance of specific information can vary greatly from person to person. What one individual might deem crucial,

another may find less relevant. This variability complicates the idea of a standardised list of information that is applicable to all patients.

16. Therefore, in our view, care should perhaps be taken as to ensure that patients do indeed receive updated information tailored to their situation.

17. One possibility is to, *via* amendment of the Code, mandate particular *pro forma* information sheets to be provided to patients. This has the advantage of ensuring uniformity and ease of compliance.

18. However, providing *pro forma* information sheets may be difficult given the rapidly changing technology and also the need to tailor the information to specific patients. The administrative burden of revising the Code regularly may also be considerable.

19. On balance, therefore, it appears to make more sense to shift the responsibility to provide relevant and up-to-date information to healthcare providers, and put it to them to tailor the counselling process to the individual needs of service user. The information provided to the patients should be properly recorded as part of the counselling records as *per* Proposed Principle 1, together with any questions raised by the patient and the responses given.

20. As regards **Proposed Principle 2**, similar to our observations in relation to Proposed Principle 1, any additional counselling after another five years should document the up-to-date information provided by the healthcare provider, the questions raised by the patient, and the responses given.

21. We do not otherwise have comments on the proposals.

Hong Kong Bar Association

Dated: 11 April 2025