Updated as at 25 June 2023

Healthcare Services (Assisted Reproduction Service) Regulations FAQ

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General

1. Must an Assisted Reproduction (AR) licensee also hold an Outpatient Medical Service (OMS) licence under HCSA?

- An AR licensee does not need to concurrently hold an OMS licence if the AR licensee only provides services within the scope of the AR Service at its premises, that is, from first consultation till confirmation of viable pregnancy post embryo transfer.
- However, if an AR licensee intends to provide, at the same premises, clinical care beyond procedures which involve the handling of gametes & embryos and which falls under the scope of the Outpatient Medical Service, such as obstetrics and gynaecology services or artificial insemination procedures , they would need to hold an Outpatient Medical Service licence.
- To facilitate AR licensees' transition to the HCSA, we will be issuing all licensees with both the AR Service licence and Outpatient Medical Service licence up till the point of the next renewal. This ensures that the licensees' scope of service remains unchanged from the PHMCA.

2. Can the AR licensee be the Clinical Governance Officer?

- Yes, to provide operational flexibility, a single person can be the licensee, Principal Officer, Key Appointment Holder and Clinical Governance Officer so long as the person meets the relevant requirements for the respective roles, and is able to dedicate enough time and attention to discharge the corresponding responsibilities.

3. What is an "adequate number" of staff?

- All AR licensees must employ at least:

  a) one suitably qualified medical practitioner to perform clinical work; and

  b) two suitably qualified embryologists to perform laboratory work, one of which must meet the criteria for a "Chief Embryologist".

  MOH does not intend to prescribe a specific number as staffing decisions vary from licensee to licensee and depends on various factors, including operational needs. The licensee is responsible for making the appropriate staffing decisions to ensure delivery of safe, effective and good quality service.

Requirements relating to Personnel

4. What criteria must the medical practitioner meet to perform AR procedures independently?

- A Licensee may engage or deploy a medical practitioner who has met **all** of the following criteria, to perform AR Procedures:
  a) is a fully registered medical practitioner under section 20(1) or (2) of the Medical Registration Act and holds a valid practising certificate under that Act;
  b) is registered under section 22 of the Medical Registration Act 1997 as a specialist in obstetrics and gynaecology;
  c) has at least 18 months of training in the provision of a local assisted reproduction service, during which the medical practitioner was trained in all of the following:
     i. reproductive endocrinology, particularly in the use of ovulation-inducing agents and hormonal control of the menstrual cycle;
     ii. ultrasound-guided oocyte collection techniques;
     iii. gynaecological endoscopy;
     iv. oocyte and embryo transfer;
  d) has at least 6 months of practical hands-on experience under the supervision of an experienced assisted reproduction practitioner in a local assisted reproduction service;
  e) has satisfactorily performed not less than 20 oocyte collection procedures and 20 embryo transfers under the supervision of an experienced assisted reproduction practitioner;
  f) has attended at least one course or seminar on assisted reproduction;
  g) has been assessed by the Clinical Governance Officer to possess the competencies required to do any act as a medical practitioner without the supervision of an experienced assisted reproduction practitioner.
- Medical practitioners who have met the requirements stated above are allowed to practice independently, but are not allowed to provide supervision unless additional requirements are met (see FAQ 6).

5. What criteria must a medical practitioner meet to provide supervision to those undergoing training (i.e., is considered an "experienced AR practitioner")?

- To be able to provide supervision, the medical practitioner must
  a) first meet all the requirements stated in Question 4;

b) have an additional 6 months of independent hands-on experience with a local assisted reproduction service; and

c) be assessed by the CGO to be able to perform AR procedures independently.

- To avoid doubt:

a) Medical practitioners who have met the requirements stated in Question 4 are allowed to practice independently, but are not allowed to provide supervision.

b) The additional 6 months of independent hands-on experience is counted only after the requirements in Question 4 are met. This means medical practitioners should have practiced for a minimum of 2 years prior to being able to provide supervision.

6. Which medical practitioners must remain under supervision?

- Medical practitioners who have not met one or more of the criteria stated in Question 4 are to be supervised when performing any AR procedure.
- Despite meeting all the criteria in Question 4, the Clinical Governance Officer can continue to place a medical practitioner under supervision if they deem the medical practitioner to not be competent enough to practice independently.

7. What criteria must an embryologist meet to perform embryology procedures independently?

- A Licensee may engage or deploy an embryologist who has met **all** of the following criteria, to perform embryology procedures:

a) holds a Bachelor of Science degree or an equivalent qualification;

b) has at least 6 months of practical hands-on experience in carrying out the embryology procedures under the supervision of an experienced embryologist;

c) has satisfactorily performed not less than 50 each of every embryology procedure under the supervision of an experienced embryologist;

d) has attended at least one course or seminar on assisted reproduction;

e) has been assessed by the Clinical Governance Officer to possess the competencies required to carry out embryology procedures without the supervision of an experienced embryologist.

- Embryologists who have met the requirements stated above are allowed to practice independently, but are not allowed to provide supervision unless additional requirements are met (see FAQ 8).

8. What criteria must an embryologist meet to provide supervision to those undergoing training?

- An embryologist must meet
  a) all the criteria listed in Question 7; and
  b) have at least 3 years of experience working with any local AR licensee.
- As with medical practitioners, embryologists who have met the requirements stated in Question 7 are allowed to practice independently, but are not allowed to provide supervision.
- The three years of experience is counted concurrently with the other requirements in Question 7.

9. Are the requirements for a chief embryologist in addition to the requirements for an embryologist?

- Yes, the requirements for a chief embryologist are in addition to those for an embryologist. This means that the chief embryologist must have had an additional 2 years of independent practicing experience as an embryologist, and have independently performed embryology procedures for 300 AR cycles, before they can be appointed as a chief embryologist.
- Embryologists cannot be appointed as the chief embryologist if they have ceased work for a consecutive period of 6 months within the 2 years of independent practice immediately before the appointment.
  a) For example, an embryologist who is to be appointed as chief embryologist on 1 July 2023 cannot have stopped working for a period longer than 6 consecutive months at any point in time between 1 July 2021 to 30 June 2023.

10. Can the AR licensee appoint the same registered nurse to oversee nursing care and provide post-procedure monitoring?

- Yes, the same registered nurse overseeing nursing care can also provide post-procedure monitoring.

Requirements relating to the provision of service

11. Are AR licensees allowed to perform artificial insemination procedures, such as Intra-Uterine Insemination?

- The AR service scope ***excludes*** the provision of artificial insemination procedures such as Intra-uterine insemination (IUI). To provide any artificial insemination procedure, such as IUI, AR Licensees must also hold an Outpatient Medical Service licence.
- To avoid doubt, oocyte stimulation which was performed as part of the patient's IUI treatment will be seen as provision of IUI, even if the patient is not intending to undergo IUI with the licensee.

12. Can AR licensees who hold an Outpatient Medical Clinic Licence perform artificial insemination procedures? Can such procedures be performed on single or divorced women

- AR licensees who hold an Outpatient Medical Clinic Licence can perform artificial insemination procedures, but only on married women. AR licensees are also reminded to comply with the Licence Conditions on the provision of Artificial Insemination Procedures.
- Even if an AR Licensee holds an Outpatient Medical Service licence, they are not allowed to perform IUI on women who are not legally married (i.e., single or divorced).This is similar to the requirement that AR procedures cannot be carried out on women who are not legally married.

13. Are AR licensees allowed to start the provision of an AR procedure/s for patients who intend to complete the procedure/s overseas?

- AR licensees are allowed to initiate service provision to patients who are intending to complete their AR procedure overseas, but only where the intended AR procedure is conducted in line with the regulatory requirements. Provision of part of the service is no different from providing the procedure itself.
- For example, AR licensees can initiate oocyte stimulation for women aged 37 to undergo EEF overseas, as the woman falls within the age limits. However, AR licensees are <u>not</u> to initiate oocyte stimulation if the woman is above the age limits, unless MOH has provided exceptional approval to carry out EEF.
- Similarly, if the patient is intending to undergo IUI, and the AR licensee does not hold an Outpatient Medical Service licence, they are not to conduct any oocyte stimulation which may be required for IUI to take place at another Ob-Gyn clinic. The patient should be referred to the relevant healthcare provider for the treatment.

14. What is counselling and when must AR licensees refer patients for counselling?

- Counselling in relation to an AR procedure refers to the provision of adequate psychosocial support to patients and their husbands. AR licensees are required to inform and offer all patients and their respective husbands on the availability of counselling. AR practitioners are also required to assess and refer their patients or their patients' husbands (if applicable) for counselling if required at any point during their AR treatment.
- Counselling differs from the provision of pertinent information to patients and their husbands prior to obtaining consent for the AR procedure, as required under the AR Regulations. Such pertinent information includes:
  a) the applicable examination and treatment procedures required before or after the assisted reproduction procedure is performed;
  b) the possible consequences and side effects of the assisted reproduction procedure;
  c) where the assisted reproduction procedure is the transfer of embryos — the number of embryos that will be transferred;
  d) any additional information or increased risks (including risks to the child conceived through the assisted reproduction procedure) that is relevant based on the age of the patient, or the number of stimulated cycles the patient has already undergone;
  e) the estimated financial costs of the assisted reproduction procedure and all other relevant examination and treatment procedures and medication.

15. Can AR licensees administer anaesthesia (including General Anaesthesia) on patients undergoing AR procedures?

- Yes, AR licensees can administer anaesthesia (including general anaesthesia) on patients undergoing AR procedures, subject to being able to fulfil the relevant regulatory requirements, including having patients first assessed by an anaesthesiologist to be suitable for administration of anaesthesia, and ensuring adequate post-procedural monitoring.
- AR licensees which are not able to fulfil these requirements may wish to refer or send their patients to an acute hospital licensee or another local AR centre which is able to fulfil such requirements.

16. If a patient is deemed unsuitable to undergo GA at an AR centre, can the AR licensee refer the patient to an Ambulatory Surgical Centre?

- Yes, but only to an Ambulatory Surgical Centre which holds an Assisted Reproduction Licence to provide AR procedures.
- AR licensees themselves are already subject to requirements which are largely aligned with those of the Ambulatory Surgical Centre. If an AR

licensee assesses that the patient is unable to be managed at their AR centre or if an AR licensee is unable to meet the imposed requirements, AR licensees are strongly encouraged to refer such patients of higher risk to the acute hospital to undergo the procedure and for post-procedure management.

17. What are the changes to the HIV testing protocol?

- We have reviewed feedback from our experts and are aware of the advancements in testing technology. With effect from 26 June 2023, patients and their respective husbands undergoing AR treatment need only be screened for HIV prior to joining the AR programme. They will no longer be mandated to undergo repeated screening while on the AR programme. These changes are aligned with the current National HIV Testing Recommendations.
- However, donors are required to undergo screening and a repeat screening, with the repeat screening no earlier than 3 months from the time of donation. Couples must be counselled and acknowledge risks of infection if they use the reproductive cells or embryos before the repeat screening test.
- As AR licensees are required to ensure that the cross-contamination of embryos and reproductive cells is prevented, AR licensees are highly encouraged to screen individuals at any point during AR treatment if the individual has been assessed as engaging in high-risk behaviour. AR licensees are also required to ensure that embryos and reproductive cells with an unconfirmed test result are required to be separately stored from those which have tested positive or negative.

18. Why must donors be screened twice? Why is there a 3-month interval between screenings for donors when HIV tests have become more sensitive?

- Donors may be anonymous, and it is not known if anonymous donors engage in behaviour that exposes them to a higher risk of contracting infectious diseases. The requirement for repeat screening ensures that the infection status of the donor is known prior to the patient undergoing AR treatment.
- The 3-month interval is to ensure that the repeat screening is definitive for >99% of infections. MOH continues to review international literature surrounding the accuracy of the HIV test kits, and will update the testing interval where required.

19. Do AR licensees need to capture the full birth certificate number of children conceived through IVF?

- Yes. Capturing the full birth certificate number of the child would allow for accurate re-identification should there be any incidents/mix-ups. Should AR

licensees face challenges in obtaining the required data from couples, AR licensees can explain the rationale for obtaining such information to couples and reassure them on the safeguards that AR licensees have put in place to protect the confidentiality of such data collected. This would allow the AR licensees to better manage couples' expectations.

20. What should AR licensees do if patients do not wish to provide the birth certificate number of children conceived through IVF due to privacy concerns?

- AR licensees are required to inform the patient that they (the AR licensee) are required to keep the register of live births under the AR Regulations.
- We understand there will be cases where it is difficult to obtain the birth certificate number, such as the patient becoming uncontactable or refusing to provide the birth certificate despite explanation. If the birth certificate number could not be obtained despite multiple reasonable attempts, AR licensees are to clearly document the reason why the couple did not provide the information.

21. Is the digital image of the marriage certificate obtained from the Singpass of the husband and wife (e.g. both husband and wife physically login into their respective Singpass in front of the clinic staff) sufficient proof of the marital status of the couple?

- AR licensees can verify the marriage status of the patient and her husband through Singpass. However, AR licensees are reminded that they are required to retain documentary proof of marriage and produce such proof where required by MOH. Such documentary proof of marriage is not limited to the physical copy of marriage certificate, and digital forms are acceptable (e.g. a screenshot of the information from the Singpass app).

22. Do AR licensees who provide point-of-care testing service in the AR Centre need to apply for a clinical laboratory service licence?

- If an AR licensee provides testing only for its own patients where (i) it is incidental to the AR licensee's management of its patient and (ii) the test only involves the use of a simple in vitro diagnostic test[1], the licensee does not need to apply for the clinical laboratory service licence.
- If the AR licensee accepts any patient from any referrals outside of its own AR centre or specimens referred from another outpatient medical service / AR licensee to conduct these tests, the clinic will need to apply for a clinical laboratory service licence.

[1] "simple in vitro diagnostic test" means an in vitro diagnostic test that is designed to return a test result without the need to interpret raw test data and requires —

(a) no specimen processing;

(b) no more than 3 steps of analytical test procedures;

(c) the use of self-contained reagent cartridges or strips or no precise measurement required for reagent preparation;

(d) no specifications for a controlled testing environment for returning an accurate test result; and

(e) only portable analysers with automated calibration, quality control and self-diagnosing malfunction features when used;

23. Do AR licensees which perform image-guided procedures (e.g. for oocyte retrieval) as part of their assisted reproduction service need to apply for a radiological service licence?

- AR licensees will not need to hold a radiological service licence to perform any ultrasound-guided procedures. AR licensees will be required to adhere to the relevant regulatory requirements and licence conditions imposed for the provision of such services.
- However, a radiological service licence will be required if AR licensees intend to perform image-guided procedures using any other imaging modality besides ultrasound (e.g. using fluoroscopy, CT).

24. Can nurses conduct ultrasound imaging?

- Yes, nurses may conduct ultrasound imaging, so long as they are under the supervision of any of the following of the AR Licensee's personnel:
  a) A medical practitioner
  b) A radiographer
  c) A sonographer

25. When may donor embryos be used?

- AR licensees are to ensure that a genetic linkage to one of the intended birth parents is met where possible. This means that the reproductive cells of the intended birth parents should always be used in the creation of an embryo, unless viable gametes cannot be obtained from both parents.
- If birth parents are able to produce viable gametes, but there are extenuating clinical circumstances which may warrant the use of donor embryos, AR licensees may submit the case to MOH for review.

26. Sex-selection of embryos is prohibited, except where a qualified assisted reproduction practitioner assesses that there is a clinical need to do so. What is an appropriate "clinical need"?

- The qualified AR practitioner must assess that the clinical need is significant and grave enough to warrant sex-selection, for example – to prevent the

transmission of serious hereditary sex-linked conditions which may result in the offspring being born with a high risk of mortality.

- If AR licensees assess that there is clinical need to carry out sex-selection of embryos, they are to write into the Director-General of Health with the specific clinical justifications on why sex-selection is required to be carried out. AR licensees are also reminded to seek the Director-General's approval before importing or transferring any sex-revealed embryo into the body of the woman (see Q31 below).
- AR licensees are prohibited from conducting sex-selection on non-medical grounds for patients, such as for family balancing.

27. What services can AR licensees provide remotely?

- AR licensees may provide the following services remotely:
  a) Clinical care that is incidental to any AR procedure, and
  b) Donor questionnaires
- Where the licensee intends to provide incidental clinical care remotely, the licensee must first conduct a clinical assessment of the patient in person at any of the licensee's approved permanent premises to ensure the patient is suitable for remote provision of clinical care, and the patient's safety is ensured. Examples of these include ensuring the patient's condition is stable enough and that the patient has the ability to receive remote provision (has working internet / devices).
- Where the licensee intends to conduct donor questionnaires remotely, the licensee needs to ensure that the information filled out in the questionnaires is kept secure and confidential.

28. Can AR licensees provide the required information on the AR procedure to patients remotely?

- Where possible, provision of required information on AR procedures to the couple before obtaining consent should be done in-person, as this minimises the risk of miscommunication. However, where this is not possible, the licensee must first conduct a clinical assessment of the patient in person at any of the licensee's approved permanent premises to determine the suitability of the patient to undergo counselling remotely.
- Licensees are strongly encouraged to provide all required information on AR procedures to the patient and, if applicable, her husband, in the patient's first in-person session as this minimises the risk of miscommunication.

29. Can AR licensees take consent remotely?

- Obtaining consent from the couple should be done in-person, as this minimises the risk of miscommunication or erroneous verification of identities. This can be done during the patient's in-person consultation.
- If this is not possible, the licensee must first conduct a clinical assessment of the patient in person at any of the licensee's approved permanent premises to determine the suitability of the patient to undergo counselling remotely.
- The licensee must also ensure that they are able to accurately verify the patient's and her husband's identities when taking such written consent and retain a copy of the written consent. Otherwise, the licensee should obtain written consent in-person.

30. Can Telemedicine be used for witnessing?

- Yes, telemedicine can be a means of witnessing. However, should the AR centre wish to use telemedicine as a means of witnessing, it must have a written SOP for the remote conduct of witnessing, use it systematically, and also ensure that all the relevant details regarding the witness (e.g., identifiers, relationship with patient) are properly captured in the express written consent obtained from the patient.)

Pre-implantation Genetic Testing

31. Must an AR licensee apply for approval to provide pre-implantation genetic testing (PGT) services?
• Yes, as PGT services are considered specified services under HCSA, AR licensees must apply for approval to provide PGT services, and must abide by the Licensing Conditions for PGT services if approved to provide these services. • To avoid doubt, AR licensees are to also write in to MOH if they intend to provide any new AR service.
32. When will PGT-A (also known as PGS) be mainstreamed?
• PGT-A will continue to be available to patients as a pilot study.
33. Are AR licensees allowed to import embryos with gender revealed?
• Embryos with gender revealed are not allowed to be imported without prior approval of the Director-General (Health). • Please refer to Q26 on sex-selection.

Gamete Freezing

34. Who can undergo oocyte freezing?

- The following groups of women can freeze their oocytes at an AR centre:

  a) A woman who has a medical condition or is undergoing medical treatment, either of which will significantly, permanently and adversely affect their fertility;

  b) A married woman who is undergoing AR treatment, and is freezing her oocytes as part of her AR treatment (for example, in the event the husband is unable to produce a sperm sample on the day of oocyte collection); or

  c) A woman who is between 21 and 37 years old.

35. Who can undergo sperm freezing?

- The following groups of men can undergo sperm freezing at an AR centre.

  a) A man who has a medical condition or is undergoing medical treatment, either of which will significantly, permanently and adversely affect their fertility;

  b) A married man who is storing his sperm for his wife (the patient) to undergo AR treatment (see Q36); or

  c) Anonymous donors donating to one of the three public sperm banks.

36. Can the husband undergo sperm freezing prior to AR treatment, if he is not able to be present during the treatment (e.g. overseas)?

- To facilitate couples' IVF treatment, sperm freezing will be permitted so long as the couple is legally married, and intending to undergo, or is undergoing, IVF. MOH has made this option available based on feedback from couples on circumstances faced when undergoing IVF treatment. This includes where the spouse is based for overseas for a long term or is unable to produce a sample on the day of the IVF procedure.
- AR licensees are reminded that they are otherwise only allowed to store gametes and embryos where medically indicated, with the exception of elective egg freezing (EEF).

37. Will elective sperm freezing be allowed?

- Sperm freezing will continue to be allowed only where medically indicated, as there is insufficient evidence at this time that male fertility reduces drastically after a certain age.

38. Previously the upper age limit for EEF was announced as 35 years of age. What is the reason behind increasing it to 37? Will the age limit be raised further?

- We regularly assess the scientific evidence behind our various policies, and whether there is professional consensus on it. Since the announcement at the White Paper last year, MOH has assessed international evidence and understands that it is acceptable to increase the age limit to align with the growing scientific evidence that success rates of egg freezing continue to remain relatively stable up to 37 years old. This also takes into consideration the scarcity of egg donors and decreasing total fertility rate.
- In other words, the likelihood of achieving live-births appears not to be significantly lower when freezing eggs at age 37 compared to age 35 . The raising of age limits additionally takes into account that demographically, women aged 35-39 undergo the greatest number of IVF cycles locally.
- As the egg donor age limit will be increased to 37, the upper age limit for EEF will accordingly be set at 37 in view that the same consideration of egg quality underlie both requirements.
- In terms of further raising of the age limit, we will continue to monitor developments in this area. The age limits will continue to be determined by international scientific evidence and local data.

39. I am 37 years old currently and will have been eligible for EEF but by June 2023, I will be above 37 years and no longer eligible. Will MOH consider allowing a woman above 37 years of age to undergo elective egg freezing?

- MOH is prepared to consider appeals from women who are slightly above the upper age limit of 37 years old when EEF is implemented together with the AR Regulations in June 2023. Such appeals will be assessed on a case-by-case basis.
- Women who wish to appeal to MOH should seek their AR practitioner's assistance to appeal on their behalf. More details will be provided to AR licensees in due course.

40. Which AR licensees can provide EEF?

- All AR licensees will be allowed to provide EEF upon its implementation. However, it remains the prerogative of the AR Centre to decide whether or not to offer the service. Women intending to undergo EEF may refer to the listing of AR licensees on the MOH Healthcare Institution (HCI) directory at www.hcidirectory.gov.sg and check with their preferred AR Centre on whether the service is provided.

41. Is there financial support for EEF?

- Couples will not be able to tap on subsidies, co-funding, or MediSave for egg retrieval and/or storage for EEF, as EEF is not a medically indicated procedure.
- At the point of using the frozen eggs in Assisted Reproduction Technology (ART), eligible couples can tap on both co-funding based on the prevailing ART co-funding framework and MediSave subject to the prevailing withdrawal limits for Assisted Conception Procedures.

42. Is there financial support for medically indicated egg freezing?

- Women who undergo egg freezing on medical grounds (e.g. chemotherapy or radiotherapy treatment that may irreversibly affect fertility) can tap on MediSave, up to the prevailing Assisted Conception Procedure limits.

43. Why is there a 7-day waiting period for EEF but not for most AR procedures?

- The 7-day waiting period is intended to allow women considering EEF sufficient time to review all pertinent information provided by the AR practitioner and hence make a considered decision. There is a similar 7-day period for women aged above 45 intending to undergo AR treatment.