

CODE OF PRACTICE FOR ASSISTED REPRODUCTIVE TECHNOLOGY UNITS

Fertility Society of
Australia and New Zealand

Reproductive Technology Accreditation
Committee

(revised October 2021)





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INTRODUCTION

The RTAC Code of Practice

This Code of Practice for Assisted Reproductive Technology (ART) Units has been developed by the Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia and New Zealand (FSANZ). The purpose of the RTAC Code of Practice is to:

- a) Promote continuous improvement in the quality of care offered to people accessing fertility treatment
- b) Provide a framework and set criteria for the auditing process that leads to licencing of Organisations/ART Units that deliver fertility services
- c) Ensure the auditing process is carried out in an independent, non-adversarial and constructive manner

Fundamental to the delivery of ART services is that patients and their offspring remain the most important consideration in all decisions. Organisations/ART Units aspire to deliver services in a manner that recognises patients' cultural and individual values and beliefs, upholds their dignity and privacy, and acknowledges the rights of children born through ART to know their genetic origins and health outcomes.

In addition to sections on establishing, renaming or closing an ART Unit, the Code of Practice has two sets of criteria as defined in the RTAC Certification Scheme, namely:

- a) Critical criteria - these are audited annually at the surveillance audits
- b) Good Practice criteria - a third is audited annually in a three-year cycle

These criteria are shown below, but are included in the text of the Code of Practice in an order that is intended to make them easier to relate to within an ART Unit:

Criteria	
Critical	Good Practice
1 Compliance	1 Quality management system (QMS)
2 Personnel	2 Medical management
3 Stakeholder feedback	3 Information
4 Disaster management	4 Medication management
5 Valid consent	5 Emergency care
6 Management of infection risk	
7 Identification and traceability	
8 Donor and surrogacy requirements	
9 Cryostorage of gametes and embryos	
10 Medical and Surgical Risks	
11 Adverse event reporting	
12 Multiple pregnancy	
13 Data monitoring	
14 Data reporting	

Background

The code was first introduced in 1986 when the FSANZ produced a series of standards as a guide for ART Units. In 1987, RTAC was established and added explanatory notes to many of the original standards drawn up by the FSANZ. This initial code was revised in 1992, 1997, 2001 and 2005. It was fully rewritten in 2008 with further revisions in 2010, 2014 and 2017.

In Australia, the *Research Involving Human Embryos Act 2002* defines an accredited ART centre as a 'person or body accredited to carry out assisted reproductive technology by the Reproductive Technology Accreditation Committee of the Fertility Society of Australia and New Zealand'. Under this Act, a person commits an offence (imprisonment for 5 years), if the person 'intentionally uses, outside the body of a person, a human embryo that is not an excess ART embryo; and the use is not for a purpose relating to the assisted reproductive technology treatment of a person carried out by an accredited ART centre'. As a result, it is currently an offence in Australian Commonwealth law to use human embryos in any way without RTAC licensing.

In all Australian States and Territories, compliance with the RTAC Code of Practice is mandatory for Units involved in the treatment of patients using ART.

In New Zealand, the HART Act 2004 governs the delivery of ART services. The NZ Ministry of Health mandates clinics attain certification against NZS 8134:2021 – *Health and Disability Services Standard*.

In New Zealand compliance with the RTAC Code of Practice is not mandatory for units involved in the treatment of patients.

RTAC Certification

An ART Unit's compliance with the RTAC Code of Practice must be reviewed regularly. An ART Unit includes associations, agencies, groups, independent practitioners and individuals accountable for the delivery of services to the patient.

The review is conducted as an audit by an independent Certification Body (CB) that is approved by the Joint Accreditation System of Australia and New Zealand (JAS-ANZ). The process for RTAC certification is defined in the RTAC Certification Scheme, and the RTAC Code of Practice should therefore be used in conjunction with the RTAC Certification Scheme.

Assisted Reproductive Technology (ART)

ART involves clinical treatments; counselling services; and laboratory procedures for the assessment and preparation of human oocytes, sperm or embryos. ART includes in vitro fertilisation; gamete intrafallopian transfer; intracytoplasmic sperm injection; embryo or gamete cryopreservation; surgical sperm recovery; oocyte, semen or embryo donation; embryo biopsy or non-invasive sampling for preimplantation genetic testing (PGT); gestational and traditional surrogacy and intrauterine insemination (IUI).

The definition of an ART Unit is in section 4 Definitions.

Scope of the Audit

The scope of the audit by a CB will include site visits to all ART Units.

Certification Scheme

The RTAC Certification Scheme details the requirements and procedures for the certification of ART Units to the Code of Practice. ART Units holding a current RTAC Certification issued by a JAS-ANZ accredited RTAC Certification Body will be eligible for RTAC consideration for recognition as an RTAC licenced ART Unit.

The Code of Practice is to be observed in ART Units involved in the treatment of patients with assisted reproductive technology including donated gametes or embryos, surrogacy and IUI.

Certain ART Units in Australia and New Zealand have also been designated by the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) as training units for the subspecialty of reproductive endocrinology and infertility. The additional requirements of those units are beyond the scope of this Scheme.

Compliance

ART Units must also comply with relevant legislation and regulations. In rewriting the Code, RTAC has attempted to align it with the regulatory and legislative requirements. However, there may be differences in detail between this Code, National Health and Medical Research Council (NHMRC) ART guidelines, and legislation and associated regulations relevant to ART that have been proclaimed by various governments. In such cases, as a general rule, national legislation overrides state legislation, and state legislation overrides regulations/guidelines and the RTAC Code of Practice.

Technical Bulletins

From time to time RTAC will become aware of issues, questions or comments where it may consider assisting units to enhance the quality of their service to patients. A Technical Bulletin (TB) is an educational communication to all ART Units, and Certifying Bodies offering advice and guidance. Technical Bulletins are not enforceable. From time to time a TB will be incorporated into the Code of Practice. From that time the TB ceases and will be removed from the website and the incorporated content is now an enforceable part of the Code. From time to time a TB will be updated as new information becomes available. The new version supersedes any older version and the new version represents the views and advice from RTAC. Older versions will either be removed from the website or marked as superseded. A list of current Technical Bulletins can be found at <https://www.fertilitysociety.com.au/code-of-practice/#tech>

1 Structure and administration

1.1 Establishment of an ART Unit

The Unit must ensure compliance with the RTAC Certification Scheme and the RTAC Code of Practice (Refer also to the RTAC Certification Scheme).

The primary audit conducted by a Certifying Body on a new ART Unit before it opens and before it receives a license from RTAC must include:

- a) Compliance with all aspects of the RTAC Code of Practice except for treatment records and outcome data analysis
- b) Fully documented policies and procedures for each area of the Organisations/ART Unit e.g. including but not limited to clinical, nursing and medication management, laboratory, counselling and administration
- c) A fully documented Quality Management System
- d) A fully documented Risk Assessment and Management Policy and records of identified risks and their management strategies
- e) Evidence that all proposed equipment for use in the ART Unit, in particular laboratory, drug storage, clinical and sterilisation equipment, has been validated
- f) Records of an internal audit to verify compliance with these requirements performed by ART Unit personnel before the Certifying Body audit
- g) RTAC must provide details of all newly established ART Units to the ANZARD custodian within 20 working days of the newly established clinic licencing

The certifying body will perform a further inspection within six (6) months after operational procedures have commenced.

1.2 Quality management system (QMS) (Good Practice Criterion 1)

The ART Unit must have a management system allowing planned, implemented, coordinated, and appropriate service delivery that meets the needs of all stakeholders. It must provide evidence of:

- a) A Quality Management policy that:
 - i) Demonstrates management commitment
 - ii) Outlines the scope of services provided, including identification of key, outsourced personnel and services
 - iii) Shows Organisations/ART Unit objectives
- b) Management review at planned intervals, to ensure the ongoing suitability, adequacy and effectiveness of the quality management system, and its alignment with the strategic direction of the ART Unit.
- c) Records management:
 - i) Compliance with statutory and regulatory authorities
 - ii) Document control system showing evidence of implementation, approval and review of internal and external documents
 - iii) Systems of internal communication including copies of meeting minutes, emails and memos
- d) Personnel training and competency:
 - i) Staff and/or contractors with appropriate and documented expertise to cover all aspects of the Organisations/ART Unit services
 - ii) Identification of training and education needs
 - iii) Records of induction, training and ongoing education
 - iv) Records of relevant professional registration
 - v) Outline of responsibility and authority
 - vi) Policies and procedures for training and ongoing competence assessment to cover aspects assessed, the frequency of assessment and the required achievement levels
 - vii) Competency criteria including skill, education, training and experience
 - viii) Records of competency for all services both internal and external
- e) Buildings and facilities:
 - i) Adequate facilities and equipment to meet the requirements of the Organisations/ART Units objectives
 - ii) Records of QC validation, maintenance and service of equipment including the frequency of testing. In the absence of a policy, the default policy will be that defined in the current NATA Medical Testing Field Application Document

- iii) Security, particularly to protect the confidentiality of records and the integrity of gametes and embryos
 - iv) All facilities where surgical procedures are conducted within an ART Unit need to provide evidence of policies and procedures to manage patient safety and assess risk
 - v) Records of service agreements with key contractors and key contracted service providers
- f) Risk management:
- i) Assessment of risks
 - ii) Review of risk
 - iii) Incident reporting and response
 - iv) Corrective and preventative action
- g) Workplace health and safety
- h) Auditing:
- i) Audit schedule
 - ii) Internal audits in compliance with the audit schedule
 - iii) Annual RTAC surveillance audits to be scheduled more than 30 days before the expiry date of their RTAC licence
 - iv) A designated Quality Coordinator who:
 - a. Is responsible for the ongoing maintenance of the quality management system with input from all personnel
 - b. Has knowledge of quality management systems

1.3 Compliance (Critical Criterion 1)

The Organisations/ART Unit must comply with statutory and regulatory requirements and provide evidence of:

- a) Identification and compliance with national and state-based statutory and regulatory requirements regarding ART treatment including statutory storage periods; donation of gametes or embryos; surrogacy; record keeping; and reporting requirements. This must be in the form of a risk assessment with clear pathways and evidence of discussion by top management, communication of any changes through documentation and staff training, and valid consent forms
- b) How changes to external requirements are integrated into work practices
- c) Communication, implementation, and review of all policies/procedures
- d) Compliance with the RTAC Code of Practice
- e) Compliance with any applicable national, state or territory legislation
- f) Records of current signed Deed of Agreement with the FSANZ
- g) All human research has been approved by a Human Research Ethics Committee (HREC) registered with NHMRC, and operating under the *National statement on ethical conduct in human research* (2007 or more recent review). In New Zealand, research having been approved by a Health and Disability Ethics Committee (HDEC) or the Ethics Committee on Human Reproduction (ECART)
- h) Compliance with the NHMRC *Ethical guidelines on the use of ART in clinical practice and research* (2017 or more recent review), except where in conflict with legislation, or where alternative requirements have been directed by a registered and compliant HREC affiliated to the Unit. In New Zealand, compliance with guidelines and advice issued to ECART by the Advisory Committee on Assisted Human Reproduction (ACART)
- i) Compliance with NHMRC infection control guidelines for Units operating within Australia

1.4 Personnel (Critical Criterion 2)

The Organisations/ART Unit and its management must show a commitment to adequate staffing, training and ongoing education.

The requirements for the senior positions are considered in two different situations, namely where the key personnel are (i) on-site, and (ii) off-site. Personnel appointed before 1 October 2017 and fulfilling the RTAC Code of Practice requirements existing at that time will be exempt.

1.4.1 Key personnel

The Organisations/ART Unit must appoint, or ensure access to, a Medical Director, a Scientific Director, a Nurse Manager and a Senior Counsellor. Key personnel are expected to attend in-person annual RTAC licensing audits of ART Units or groups of ART Units for which they are responsible. Where the Medical Director has clinical obligations on the day, he/she must make time available for discussions with the auditor. The ART Unit must provide evidence of qualifications, training, education and experience of key personnel.

Key Personnel must be involved in and responsible for policies and procedures in their area of responsibility.

RTAC and the relevant Certifying Body must be notified of all changes to Key Personnel within 30 days. A CV of the new appointee must also be supplied.

1.4.1.1 Medical Director

The Medical Director is responsible for the clinical management within the Organisations/ART Unit and the training, competency, and supervision of all clinicians involved in the Organisations/ART Unit. The Medical Director must be a recognised specialist gynaecologist or physician who;

- a) Has at least five years' experience in that role; or
- b) Can demonstrate substantial similar experience in the governance of an ART Unit and the management of patients with infertility; or
- c) Holds a Certificate of Reproductive Endocrinology and Infertility (CREI)
- d) Membership or eligibility for membership of the FSANZ is required.

The Medical Director must provide evidence of Fellowship of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) or the Royal Australian College of Physicians (RACP) and demonstrate continuing medical education in the field of reproductive endocrinology and infertility. For non-CREI holding Medical Directors, at least 50% of the minimum required CME points in their College-mandated CME programmes must be obtained in the area of reproductive medicine and infertility.

1.4.1.2 Scientific Director

The Scientific Director is responsible for the scientific management within the ART Unit and the training, competency, and supervision of all scientific staff involved in the Organisations. The Scientific Director must have experience in the management of clinical embryology or clinical andrology laboratory as appropriate to services offered and must possess demonstrable knowledge of and continuing education in all laboratory aspects of the Organisations. The Scientific Director must:

- a) Demonstrate knowledge of and continuing education in all laboratory aspects of the Organisations
- b) Must also have a minimum of four full-time equivalent years of ART clinical laboratory experience in an RTAC-accredited clinic (or equivalent) and two full-time equivalent years of experience in a managerial and/or supervisory role
- c) Have experience in the management of clinical embryology or clinical andrology laboratory as appropriate to services offered
- d) Have a doctorate (PhD) from an accredited institution in reproductive biology, or a Master's degree (MSc) with expertise and/or specialised training in the physiology of reproduction, cell biology and biochemistry, and experience in experimental design, statistics and problem solving
- e) For scientists in Australia certification with the Australian Council for Certification of the Medical Laboratory Scientific Workforce (CMLS) is recommended, and in New Zealand registration as a clinical Embryologist with the Medical Science Council is required.
- f) Membership or eligibility for membership of the FSANZ and SIRT is required.

1.4.1.3 Nurse Manager

The nurse manager is responsible for the nursing management within the Organisations/ART Unit and the training, competency, and supervision of all nurses involved in the Organisations/ART Unit. The Nurse Manager must be a Registered Nurse and/or Registered Midwife with experience and training in infertility nursing and:

- a) Be registered to practice in a state or territory of Australia or in New Zealand, and
- b) Have a minimum of three years experience in the management of patients with infertility, and
- c) Demonstrate continuing nursing education in the field of infertility
- d) Is a member or is eligible for membership of the FSANZ and FNA.

1.4.1.4 Counselling Manager / Senior Counsellor

The Unit Counselling Manager/Senior Counsellor is responsible for the counselling management within the ART Unit and the training, competency, and supervision of all counsellors involved in the Organisations/ART Unit.

The Counselling Manager/Senior Counsellor must have:

- a) Full membership OR be eligible for full membership of the Australian and New Zealand Infertility Counsellors Association (ANZICA)
- b) A minimum of two years experience in the management of patients with infertility
- c) Evidence of a minimum of 10-hours of engagement in ongoing professional development in the field of ART and infertility counselling over 12 months.

1.4.2 Additional personnel

The ART Unit must provide evidence that all staff are authorised to perform the functions that they have been employed to carry out.

- a) The management and care of the patient within an ART Unit must be provided or supervised by a registered medical specialist who is a Fellow of the RANZCOG, or a Fellow of the RACP who has at least 50% of the minimum required CME points in their College-mandated CME programmes obtained in the management of fertility
- b) Supervision of trainees or general practitioners working within an ART Unit must be provided by a registered medical specialist who is a Fellow of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) or the Royal Australian College of Physicians (RACP) as above. Specialists, trainees and general practitioners must provide written evidence of training and competency in the management of fertility and continued medical education (CME) in this area
- c) Where the provision of care within an ART Unit is provided by a general practitioner or trainee, a written delegation of the scope of clinical care undertaken by the general practitioner or trainee must be made by the supervising specialist and agreed to by the general practitioner or trainee. The supervising specialist must demonstrate that documented supervision of GP or trainee is occurring. The nature and extent of this arrangement must be disclosed formally to the patient/s. Contingency arrangements in the event of an emergency must be in place

1.4.2.1 Clinical Director

The Clinical Director is responsible for the day-to-day clinical management within the ART Unit and supports the Medical Director in the training, competency, and supervision of all clinicians involved in the Organisations/ART Unit. The Clinical Director must be a recognised specialist gynaecologist who;

- a) Has at least two years experience in that role; or
- b) Can demonstrate substantial similar experience in the clinical management of an ART Unit and the management of patients with infertility; or
- c) Holds a Certificate of Reproductive Endocrinology and Infertility (CREI)
- d) Is a member or is eligible for membership of the FSANZ.

The Clinical Director must provide evidence of Fellowship of the FRANZCOG or the Royal Australian College of Physicians (RACP) and demonstrate continuing medical education in the field of reproductive endocrinology and infertility. For non-CREI holding Clinical Directors, at least 50% of the minimum required CME points in their College-mandated CME programmes must be obtained in the area of reproductive medicine and infertility.

1.4.2.2 Laboratory Manager/Supervisor

The Laboratory Supervisor must have experience in all aspects of clinical embryology or clinical andrology laboratory, as appropriate to services offered, and must possess demonstrable knowledge of, and continuing education in, all aspects of the laboratory function.

The Laboratory Manager/Supervisor:

- a) Is responsible for the training and competency of all clinical scientific staff working in that laboratory.
- b) Must have at least a Master's degree or Postgraduate diploma from an accredited institution demonstrating a broadly-based scientific experience in reproductive biology, with expertise and/or specialised training in the physiology of reproduction, cell biology and biochemistry.
- c) Must also have a minimum of two years full-time equivalent of ART clinical laboratory experience in an RTAC-accredited laboratory (or equivalent) following completion of their formal training in the services provided. Solo competent embryologists in remote geographical locations may be exempt providing that policies and procedures, together with evidence of ongoing communication, exist to ensure clear and effective support from the Scientific Director.
- d) Is recommended for scientists in Australia to obtain a certification with the Australian Council for Certification of the Medical Laboratory Scientific Workforce (CMLS). Is required for scientists in New Zealand to be registered as a clinical Embryologist with the Medical Science Council.
- e) Is a member or is eligible for membership to the FSAZ and SIRT.

1.4.2.3 Nurse Unit Manager or Senior Nurse

The Nurse Unit Manager/Senior Nurse is responsible for the nursing management within the ART Unit and supports the Nurse Manager in the training, competency, and supervision of all nurses involved in the ART Unit. The Nurse Unit Manager/Senior Nurse must be a Registered Nurse and/or Registered Midwife with experience and training in infertility nursing and:

- a) Be registered to practice in a state or territory of Australia or in New Zealand; and
- b) Have a minimum of 2 years of experience in the management of patients with infertility; and
- c) Demonstrate continuing nursing education in the field of infertility Membership or eligibility for membership of the FSAZ and FNA is required.

If no permanent Nurse Unit Manager/Senior Nurse is available, the Nurse Manager must be in regular and ongoing contact, and communication records are kept, to assist with training, policy and procedure implementation and any other licensing requirements. The Nurse Manager must also be contactable by staff at satellite centres in the absence of a Nurse Unit Manager/Senior Nurse.

1.4.2.4 Counsellor

The Counsellor must have:

- a) Full membership OR be eligible for full membership of the Australian and New Zealand Infertility Counsellors Association (ANZICA)
- b) Evidence of a minimum of 10-hours of engagement in ongoing professional development in the field of ART and infertility counselling over 12 months.

In addition, the ART Unit must ensure that proper systems are in place for record-keeping and maintaining confidentiality in keeping with ANZICA and NHMRC ART guidelines.

1.4.3 Where key personnel are off-site

In the absence of an on-site Medical Director, Scientific Director, Nurse Manager, or Senior Counsellor, the day-to-day management of that area must be undertaken by a Clinical Director, Laboratory Manager/Supervisor, Nurse Co-ordinator or Counsellor respectively. The ART Unit must provide evidence of qualifications, training, education and experience of this personnel. In addition, the ART Unit must be able to demonstrate regular involvement of the Key Personnel in clinical and quality control review of the ART Unit and its activities through documented participation in meetings (in particular management review and disaster scenario planning), correspondence or a combination of these. Off-site Key Personnel must be available for consultations (in-person, telephone or electronic) as needed by the ART Unit with a minimum of one annual in-person visit.

1.5 Stakeholder feedback (Critical Criterion 3)

The ART Unit must undertake regular stakeholder feedback. It must provide evidence of implementation and review of policies and procedures to collect, analyse, review and take relevant action on stakeholder feedback including patient stakeholders.

The ART Unit must acknowledge and investigate complaints, and provide evidence of implementation and review of policies and procedures which include:

- a) Information on how patients make a complaint and how they receive feedback
- b) Acknowledgement and investigation of complaints
- c) Systematic recording, review and corrective action of complaints

Stakeholders must be provided with avenues that allow the escalation of a complaint to persons or Organisations outside of the ART Unit.

1.6 Disaster management (Critical Criterion 4)

To minimise the risk of serious adverse outcomes following a disaster, the ART Unit must:

- a) Have contingency plans that address potential disaster scenarios including those unique to their location
- b) Ensure access to emergency equipment, power, and gas that is shown to work in critical areas such as surgical procedures and maintenance of embryo culture conditions
- c) Show documented evidence of working through scenarios
- d) Identify the principal components of the plans, and show them to be feasible and to work
- e) Show regular review of contingency plans

1.7 Renaming or Closure of an ART Unit

1.7.1 Renaming of an ART Unit

In the event of renaming, the ART Unit must notify within 30 days RTAC, the Certifying Body, the ANZARD custodian, and statutory and regulatory authorities where applicable.

1.7.2 Closure of an ART Unit

In the event of a closure, the ART Unit must provide documented evidence of the closure to all parties. within 30 days including RTAC, the Certifying Body and the ANZARD custodian and must:

- a) Ensure the ongoing safe storage and accessibility of gametes, embryos, tissues and medical records, and
- b) Inform the relevant statutory and regulatory authorities and all stakeholders (including evidence of appropriately informing patients of the closure).

2 Patient management and treatment

2.1 Medical management (Good Practice Criterion 2)

The ART Unit must ensure that it meets the reproductive health needs of the patients and partners under its care. It must provide evidence of implementation and review of policies and procedures so that:

- a) Women undergo clinical evaluation for co-existing reproductive health or gynaecological problems, or those arising as a result of ART treatment
- b) Men undergo clinical evaluation for co-existing reproductive health and related problems, including an examination of the testes, or those arising as a result of ART treatment
- c) There are pathways of referral for endocrine, andrological and psychological expertise
- d) Preconception advice must be provided to patients, including the consequences of abnormal weight, age, smoking, adverse environmental exposure and other relevant factors. This must be incorporated into referral pathways to ensure optimal health, and pre-conception psychological health, before fertility treatment

2.2 Information (Good Practice Criterion 3)

2.2.1 Patient information

The Unit must provide patients with information that is accurate, timely, in formats and language appropriate to the patient. It must provide evidence of implementation and review of policies and procedures to ensure patients receive written and verbal information covering diagnosis, investigation and fertility treatment options. Patient information must include but not be limited to:

- a) Processes, costs, risks and outcomes
- b) Drugs and side effects
- c) Availability of individual counselling and support groups
- d) Patient rights and responsibilities, as detailed in the Australian Charter of Healthcare Rights and in New Zealand the Code of Health and Disability Services Consumers Rights
- e) Availability of translation and interpreter services
- f) Preconception advice, including the consequences of abnormal weight, smoking, adverse environmental exposure, psychological issues and other relevant factors
- g) A statement that donor and surrogacy arrangements are likely to require multiple counselling sessions
- h) The use of any adjuvant therapy, if applicable
- i) Patient consenting process and how their data will be collected, stored and used

2.2.2 Open disclosure

Australian ART Units must have a policy of open disclosure consistent with the Australian Open Disclosure Framework from the Australian Commission on Safety and Quality in Health Care. New Zealand ART Units must have a policy of open disclosure consistent with the Code of Health and Disability Services Consumers' Rights available on the Health and Disability Commissioner web site, <https://www.hdc.org.nz/your-rights/the-code-and-your-rights/>

2.2.3 Public information

Information presented in the public domain must be in a language that can be understood by the lay public and ensure the overall conclusion is not misleading in any way. The information must be consistent with the following requirements:

- a) Success rates must:
 - i) Be divided by age
 - ii) Specify live birth rates for fresh and frozen embryo transfers separately. Use of clinical pregnancy rates in advertised success rates may be permissible provided that the live birth rates are also available for comparison in the same communication
 - iii) Be accompanied with the following clarifying information: the period during which the advertised data was collected and unambiguous details of the population group from which they are derived (e.g. whether they relate to IVF, ICSI, PGT or FET, and age group)
 - iv) Be accompanied by a qualifying statement of broad factors that affect success rates e.g. age, weight, and cause of infertility, and that individual results will vary with individual circumstances
 - v) Be accompanied by a statement that not every treatment cycle will result in an egg collection, an embryo transfer or embryo cryopreservation
 - vi) Ensure that any clarification, qualifying statement or reference be clear and prominent and not hidden in a disclaimer
- b) Not reference other clinics' published success rates to develop league tables or other clinic performance comparisons nor use, quote or direct visitors to any league tables published by media. IVF Clinic success rates presented on government-funded websites are for the benefit of patients and are not for commercial use. ART Units may link to the YourIVFSuccess website, but permission is restricted to linking without any alteration of the Website's contents. Permission is not granted to reproduce, frame, or reformat the files, pages, images, information and materials from the YourIVFSuccess website unless express written permission has been obtained from UNSW. Media announcements of scientific or clinical "breakthroughs" in the field of ART must only be made after a peer-review process such as presentation of an abstract for a scientific meeting or a manuscript publication in an appropriate scientific journal
- c) Any media release must provide a clear link/reference to the primary source of the facts being discussed and must avoid vague references such as "according to expert opinion". The individuals making claims must be identified.
- d) ART Units must not incorporate patient comments on social media that promote their practice or service.

- e) ART Units must have appropriate governance in place to ensure that all public information complies with the requirements of the Australian Consumer Law, as well as AHPRA and ACCC guidance, and must only release information to the public domain once its accuracy has been verified and approved by the Medical Director.
- f) Any RTAC accredited unit receiving a notification from the ACCC, AHPRA or a Department of Fair Trading of a complaint concerning advertising by the ART clinic or one of its registered health practitioners must advise the Chair of RTAC to enable monitoring of complaints by RTAC.
- g) ART Units must ensure their websites and social media platforms comply with the above requirements and document this through regular internal audits.

2.3 Valid consent (Critical Criterion 5)

The Organisations/ART Unit must:

- a) Ensure that treatment only occurs with valid consent, as defined by the NHMRC *Ethical guidelines on the use of ART in clinical practice and research* (2017 or more recent review), and in New Zealand as defined by any guidelines or advice issued by ACART
- b) Ensure that consent is written, signed and dated. Documentation must include a signed statement by the treating clinician confirming that all relevant provision of information and counselling requirements have been satisfied.
- c) Have a process whereby clinical staff ensure that valid consent is obtained from all patients, donors and/or surrogates (and, where relevant, their spouses or partners) before treatment commences
- d) Obtain consent from the patient for their de-identified patient and treatment information to be recorded in the Australian and New Zealand Assisted Reproductive Technology Database (ANZARD) and that their ANZARD information may be used for population analysis, research projects, and the publication of clinic success rates (Australian clinics only) and that the patients identifying information may be reviewed by regulatory bodies for the purpose of licensing and RTAC accreditation
- e) Ensure that where an interpreter is required a health care interpreter must be used and the use of this service must be noted on the consent. The definition of a health care interpreter is in section 4 Definitions
- f) Provide patients with information that is accurate, timely and in formats appropriate to the patient
- g) Provide evidence of implementation and review of policies and procedures which define the consenting process

2.4 Management of infection risk (Critical Criterion 6)

The ART Unit must manage the risk of infection transmission for all clinical and laboratory procedures undertaken within the ART Unit. It must have in place risk assessments, policies and procedures which ensure the minimisation of infection transmission risk:

- a) Between donors of reproductive tissues and recipients or surrogates, between partners in serodiscordant couples, and between patients and donors
- b) For staff handling biological material, including infectious disease screening
- c) Including policies for the management of all reusable medical devices in line with current standards
- d) That address hand hygiene practice in line with best practice requirements

Where applicable, policies must define quarantine periods and tests to be performed.

2.5 Medication management (Good Practice Criterion 4)

Where the ART Unit issues medications without pharmacy involvement the unit must provide evidence of implementation and review of policies and procedures to ensure the safe management of medications including:

- a) suitable equipment for storage
- b) records of medication storage temperatures
- c) records of patients receiving medications

2.6 Identification and traceability (Critical Criterion 7)

The ART Unit must ensure that gametes, embryos and patients are correctly identified and matched at all times and, in particular, ensure that men providing a semen sample confirm in writing on each occasion that the sample is theirs.

The ART Unit must provide evidence of the implementation and review of:

- a) Policies and procedures to identify when, how and by whom the identification, matching, and verification are recorded for gametes, embryos and patients at all stages of the treatment process including digital and manual record-keeping
- b) The process that constitutes the traceability of gametes and embryos at all stages of the treatment cycle and associated digital and manual records including where transport is involved
- c) Regular (at least annual) audit of the patient, gamete and embryo identification process and associated digital and manual records
- d) A minimum of three forms of identification must be used to ensure the traceability of all persons and specimens

2.7 Emergency care (Good Practice Criterion 5)

The ART Unit must ensure access to emergency care. It must provide evidence of implementation and review of policies and procedures on emergency physical and psychological care, and ensure patients and their partners receive information on how to access emergency care including out of normal hours. The ART Unit must have a policy for dealing with emergency after-hours psychological care for patients which has been developed in consultation with the Senior Counsellor.

2.8 Donor and surrogacy requirements (Critical Criterion 8)

The ART Unit must ensure gametes, embryos and tissues are safe for donation and use in surrogacy arrangements and that appropriate counselling has been provided. It must provide evidence that:

- a) the Unit will obtain a declaration from the recipient patient/couple before the initiation of the treatment cycle saying that the recipient patient/couple will provide information about the treatment cycle outcome
- b) counselling has been undertaken by a counsellor who is eligible for membership of ANZICA. For donor and surrogacy arrangements, counselling is mandatory for all donors, partners, recipients and surrogates and their partner's
- c) policies and procedures are in place, which have been developed in conjunction with the senior counsellor, concerning these treatment arrangements. For known donation, an additional joint session involving all parties must be undertaken before the signing of consents
- d) in Australia in the absence of state, legislation comply with the recommendation of the NHMRC Ethical Guidelines for family limits. In New Zealand comply with the health and disability Services Standard and guidelines and advice issued by ACART

The ART Unit must supply to the Certifying Body audit team a list of all file codes involving donation divided according to sperm, oocytes and embryos, and surrogacy, in the previous calendar year. The CB will select three (where available) from each category for a full audit on the day.

2.9 Cryostorage of gametes and embryos (Critical Criterion 9)

The ART Unit must provide evidence of implementation and review of policies and procedures to ensure the safe management of cryopreserved gametes, embryos and tissues. These records must include but are not limited to clear identification of the storage container in a form that is resistant to degradation during cryostorage, and the location of the container in the storage vessel. Records must be kept of temperature movements within the vessel that may affect the viability of any stored genetic material. Also, records must be kept including but not limited to the date of purchase of the storage vessel and its age. There must be a policy covering the monitoring of storage vessels and on detecting a failure and this must include a policy of renewal of storage vessels.

2.9.1 Transport of Cryostored material to an overseas clinic

The ART Unit must have a documented policy that deals with a request for cryostored gametes or embryos to be transported to a clinic in an international destination. This policy must ensure:

- a) The safe transport of the gametes and/or embryos by a qualified operator
- b) That the intended purpose of gametes and/or embryos is a transfer into a woman's uterus
- c) That the intended purpose is not commercial surrogacy

3 Outcomes

3.1 Medical and Surgical Risks (Critical Criterion 10)

All medical procedures involve some form of risk and ART procedures are not exempt. Some of these risks are well understood and there exist procedures to mitigate the risks for individual patients even though the risk itself cannot be eliminated. For ART procedures these risks include but are not limited to ovarian hyperstimulation syndrome (OHSS), postoperative bleeding, postoperative infection and ovarian torsion. The ART Unit must minimise the incidence of these risks. It must provide evidence of implementation and review of policies and procedures that:

- a) Enable identification and management of patients at risk
- b) Measure and attempt to minimise the incidence of these risks
- c) Ensure patients receive information on these risks, their symptoms and their management
- d) Ensure patients receive information on how to access help, advice or care out of normal hours or in the event of a medical emergency
- e) Ensure that all cases which involve re-hospitalisation that can be attributed directly to the ART procedure are reported to RTAC and the certifying body as a serious notifiable adverse event. See Section 3.2 for definition and reporting requirements. The time frame for such an event is not limited to the current treatment cycle
- f) Ensure that all cases of OHSS requiring hospitalisation are reported to ANZARD

3.2 Adverse event reporting (Critical Criterion 11)

The Organisations/ART Unit must acknowledge, investigate, report and review any serious adverse events (defined below). A serious adverse event is by definition reportable to RTAC and the Certifying Body.

The ART Unit must possess and show evidence of internal policies, and have governance mechanisms in place, to record and review any serious adverse events. If the internal or external review identifies a correctable action that the ART Unit needs to undertake to prevent recurrence of the event, the ART Unit needs to provide evidence that this is occurring.

3.2.1 Serious adverse events must be reported:

- a) As soon as practical, but no later than six weeks after the provider becomes aware of the incident. If the investigation has not been completed within this timeframe, the notification must still be submitted. A follow-up report can then be provided once the investigation has been finalised.
- b) Within two weeks for a potential or actual breach of legislation; or
- c) Within 48 hours for a sentinel event e.g death

The serious adverse event must be reported to both RTAC and the Certifying Body

The template form, **Attachment 1**, must be used for reporting.

In Victoria, the specific online form provided by VARTA for reporting also satisfies RTAC requirements.

3.2.2 A serious adverse event includes any event which:

- a) Causes a significant medical or surgical condition that occurs as a result of the ART treatment as defined in **Section 3.2.3** below
- b) Results in the hospitalisation of the patient due to a complication of ART treatment as defined in section 3.2.3
- c) Results or may result in the transmission of a communicable disease
- d) Results in a breach or potential breach of legislation
- e) Arises from a gamete or embryo identification mix up
- f) Causes a loss of viability of gametes or embryos or suspected deterioration (beyond accepted laboratory standards) that renders them unsuitable for use.
- g) Arises from a systematic failure in the validation/verification of a diagnostic test and/or technology that has resulted in misdiagnosis and/or significant potential harm or loss to patients, their gametes or embryos

3.2.3 Specific medical or surgical conditions that define a serious adverse event

3.2.3.1 OHSS is determined as:

- a) Any one of the Severe or Critical OHSS features as defined by RCOG guidelines (see table included below) and/or
- b) Where hospitalisation occurred for >24 hours and/or
- c) Where paracentesis or chest drain occurred (either inpatient or outpatient) and/or
- d) Where thrombosis occurred

3.2.3.2 Confirmed Pelvic infection

that occurred as a direct result of ART treatment (oocyte retrieval, embryo transfer or intrauterine insemination) which resulted in admission to hospital, treatment with IV antibiotics and/or surgical intervention. The initial patient presentation was within the first 4 weeks of the procedure.

3.2.3.3 Complication at oocyte retrieval

where injury to a pelvic structure occurred requiring admission to hospital and/or IV antibiotics (not prophylactic) and/or blood transfusion.

3.2.3.4 Ovarian torsion

which occurred during stimulation or within 4 weeks of oocyte retrieval and required hospital admission for > 24 hours

3.2.3.5 Complication of a sperm retrieval procedure

requiring hospital admission.

3.2.3.6 Other

A serious medical or surgical condition that resulted directly from the ART treatment and required hospitalisation that is not covered by the above 5 events. May involve admission to hospital for > 48 hours for pain, bloating, nausea where OHSS, torsion, infection has been excluded.

3.2.3.7 Severe mental health event

requiring hospitalisation in which ART was a major contributing factor and which occurred during or within 2 weeks of the completion of the treatment cycle.

3.2.3.8 Death

- a) Direct Death - a death that is directly caused by ART treatment
- b) Indirect Death - a death for which the direct cause of death was not due to ART treatment, but the ART treatment had a contributing effect
- c) Coincidental Death – Deaths from unrelated causes that happen during the course of an IVF treatment cycle
- d) Maternal death in an IVF patient is not included as this will be captured in obstetric reporting

3.2.4 Adverse events that do not meet the definition of a serious adverse event:

- a) Ectopic pregnancy
- b) Complications arising from a miscarriage
- c) Pain, bloating, nausea or other symptoms where the reportable serious events defined above for OHSS, infection, torsion etc have been excluded and hospital admission was < 24 hours

3.3 Multiple pregnancies (Critical Criterion 12)

The ART Unit must minimise the incidence of multiple pregnancies. It must provide evidence of implementation and review of policies and procedures that:

- a) Ensure a regular audit (at least annually) of multiple pregnancy rates and corrective actions that continuously attempt to reduce the incidence of multiple pregnancies in all treatment cycles, including artificial insemination even when the insemination is done offsite
- b) Recommend to patients that no more than one embryo or oocyte is transferred in the first treatment cycle where the oocyte is obtained from a woman aged less than 35 years at the time of oocyte collection
- c) Ensure that no more than two embryos or oocytes are transferred in any one treatment cycle in a woman under the age of 40 years at the time of oocyte collection
- d) Ensure that no more than two embryos or oocytes are transferred to a recipient woman, of any age, in any one treatment cycle, where the oocytes are donated from a woman aged less than 40 years at the time of oocyte collection

- e) Ensure single embryo transfer is mandatory for a gestational carrier in surrogacy arrangements
- f) Ensure that patients receive information on the risks to parents and babies associated with multiple pregnancies

3.4 Data monitoring (Critical Criterion 13)

The Organisations/ART Unit must undertake regular reviews of treatment outcomes. It must provide evidence of implementation and review of policies and procedures to:

- a) Identify, collect, analyse and review data to monitor treatment procedures and practices and treatment outcomes at least annually.
- b) Benchmark the Organisations/ART Unit's clinical outcomes against the most recent ANZARD Feedback Report and identify areas and opportunities for improvement. Where clinical outcomes fall below the 25th percentile, the unit is required to undertake a root cause analysis as to why its results fall in this range and provide a corrective action plan or provide a rationale for not doing so.

In addition, the RTAC Chair will notify the Unit when the clinical outcomes as reported to ANZARD fall below the 3rd standard deviation in a funnel plot taking into account potentially confounding factors such as the size of the ART Unit, female patient age and parity. If this occurs on two consecutive years then the ART Unit will be required to submit to the RTAC Chair an improvement plan, and its implementation will be audited by the Unit's Certifying Body at six-monthly intervals, at the Unit's cost, until there is a sustained improvement.

3.5 Data reporting (Critical Criterion 14)

The Organisations/ART Unit must (a) provide the Australian and New Zealand Assisted Reproduction Database (ANZARD) with required data in the stipulated timeframe, and (b) inform patients of the uses to which their medical information may be put. It must provide evidence of:

- a) Compliance with the relevant ANZARD Data Dictionary
- b) Accuracy of ANZARD data, including the definition of pregnancy outcome as specified in the current ANZARD data dictionary, through an internal audit before submission to the agency collecting the data, and
- c) In addition, the Organisations/ART Unit must provide at the RTAC audit a list of all cases submitted to ANZARD in the previous calendar year, and all ART treatment cycles undertaken in the current year where the outcome is known. This must include those having become pregnant and with a range of pregnancy outcomes. From this list, the CB will randomly select ten (10) for which the Organisations/ART Unit will be required to provide documentary evidence of testing verifying pregnancy outcome

4 Definitions

ACCC	Australian Competition and Consumer Commission
Adverse Events	These are defined in Sections 3.2.2 and 3.2.3
AHPRA	Australian Health Practitioner Regulation Agency
ANZARD	Australian and New Zealand Assisted Reproduction Database
ANZICA	Australian and New Zealand Infertility Counsellors Association
Appoint	When the Organisations/ART Unit employs, hires, contracts with, chooses or arranges for a particular individual to provide a certain role
ART	Assisted Reproductive Technology
Artificial Insemination	The controlled and planned ART process by which sperm is introduced into the female genital tract with or without hormonal stimulation
Organisations	An Organisation is a corporate entity that controls one or more ART Units and uses a common set of policies and procedures across all of those ART Units. These common policies and procedures need only be audited at a corporate level
ART Unit	A facility with a laboratory collecting or preparing human gametes and/or embryos for therapeutic service, possibly across a range of sites of clinical activity. Where the collection of gametes/embryos takes place at a different site to the preparation, the two sites are considered to be a single ART Unit
Audit	A systematic, independent examination and review to determine whether actual activities and results comply with planned arrangements
Authority	The proper powers to carry out an action whether granted directly or delegated
Certification	A third-party assessment of the quality system of the service provider with respect to published quality system standards and any supplementary documentation required under the system (for example ISO 19011:2018)
Competent	Having the required ability, knowledge or authority
CREI	Certificate of Reproductive Endocrinology and Infertility
Deed of Agreement	Signed agreement with the FSANZ to comply with the RTAC Code of Practice. A new agreement is required annually
Disaster	A disaster is a sudden, calamitous event that seriously disrupts the functioning of a community or society and causes human, material, and economic or environmental losses that exceed the community's or society's ability to cope using its resources. Though often caused by nature, disasters can have human origins
Facility	The physical location, site or building within or from which the service is provided
FNA	Fertility Nurses of Australasia

FSANZ	Fertility Society of Australia and New Zealand
Governance	Taking responsibility for the overall direction of the Organisations/ART Unit, including determination of the purpose and goals of the service
Health care interpreter	Trained bilingual staff, on-staff interpreters, contract interpreters, telephone interpreters, and trained volunteers can serve as health care interpreters. The following people, however, should not serve as health care interpreters: patients' family and friends, children under 18 years old, other patients or visitors, and untrained volunteers.
HIV	Human immunodeficiency virus
Integration	When the ART Unit involves, assimilates, incorporates or amalgamates individuals into its day-to-day activities
Management	Implementing the policy determined by the governing body and coordinating the day-to-day service activity which achieves the purpose and goals of the Organisations/ART Unit
Must	Where it is mandatory in every circumstance to perform the required task with no exception
NHMRC	National Health and Medical Research Council
NHMRC ART guidelines	<i>Ethical guidelines on the use of assisted reproductive technology in clinical practice and research (2017 or more recent review) issued by NHMRC</i>
OHSS – Severe*	<p>Clinical ascites (\pm hydrothorax)</p> <p>Oliguria (< 300 ml/day or < 30 ml/hour)</p> <p>Haematocrit > 0.45</p> <p>Hyponatraemia (sodium < 135 mmol/l)</p> <p>Hypo-osmolality (osmolality < 282 mOsm/kg)</p> <p>Hyperkalaemia (potassium > 5 mmol/l)</p> <p>Hypoproteinaemia (serum albumin < 35 g/l)</p> <p>Ovarian size usually > 12 cm</p>
OHSS – Critical*	<p>Tense ascites/large hydrothorax</p> <p>Haematocrit > 0.55</p> <p>White cell count > 25 000/ml</p> <p>Oliguria/anuria</p> <p>Thromboembolism</p> <p>Acute respiratory distress syndrome</p> <p><i>Reference: The Management of Ovarian Hyperstimulation Syndrome. Green-top Guideline No. 5 February 2016</i></p> <p><i>Ovarian size may not correlate with the severity of OHSS in cases of assisted reproduction because of the effect of follicular aspiration.</i></p> <p><i>*Women demonstrating any feature of severe or critical OHSS must be classified in that category.*</i></p>

Ovulation Induction	The controlled and planned ART process whereby hormonal stimulation is employed to induce the process of ovulation. Not audited
Patient	A user or participant in the service including donors.
Policy	Overall intentions and directions of an Organisations/ART Unit
Procedure	A specific way to carry out an activity
Process	A set of interrelated or interactive activities which are planned and carried out under controlled conditions
Quality Policy	Overall intentions and direction of an Organisations/ART Unit related to quality as formally expressed by top management
Records	A description of the healthcare provided for an identifiable patient/donor. Maybe a single file, multiple files, hard copy or electronic and be held by an Organisations/ART Unit, service provider or the patient/donor themselves
Review	A formal process of updating, amending, or replanning that is based on the evaluation of outcomes
Risk	The chance of something happening which will harm objectives
Risk management	The culture, processes and structures that are directed towards realising potential opportunities whilst managing adverse effects
Satellite Unit	A satellite unit is a unit that does not have a resident laboratory or laboratory facilities
Service provider	An individual who is responsible for providing the service either independently or on behalf of an Organisations/ART Unit. This includes all staff and management who are employed, self-employed, visiting, honorary, sessional, contracted or volunteer
SIRT	Scientists in Reproductive Technology
Stakeholders	Person or group having an interest in the performance or success of an Organisations/ART Unit, including but not limited to staff, patients, owners, major suppliers, funding and community Organisations
Supervision	An activity that aims to enable the supervisee to achieve, sustain and develop a high-quality practice through the means of focused support and development
Therapeutic Service	Service aimed at treating patients, such as IVF, IUI. It does not include diagnostic procedures e.g. semen analysis
Valid Consent	For consent to be valid: <ul style="list-style-type: none"> • the person giving consent must be considered to have the capacity to provide consent • the decision to consent to the treatment or procedure must be made without undue pressure • all relevant requirements regarding the provision of information and counselling requirements in Chapter 4 of the NHMRC ART guidelines must be satisfied • the consent must be specific and is effective only to the treatment or procedure for which information has been given

ATTACHMENT 1

Please supply the following information about any serious adverse event to the RTAC secretariat and your Certifying Body as required in Section 3.2 of the RTAC Code of Practice.

ART Unit name, site and RTAC licence number	
ART Unit reference number (if applicable)	
Type of event (Clinical, Laboratory, Regulatory, Compliance, Patient, other)	
Other authorities notified	
Date of Incident (This is the date the incident became apparent, for re-hospitalisation events it is the date the patient was first re-admitted to the hospital.)	
ART procedure (IVF, etc as per ANZARD)	
Date of notification (This is the date this report was sent to RTAC and the CB)	
Date of OPU, ET (if FET), or ANZARD start date if there was no OPU or ET.	
Incident description (Please include cause, how identified, severity, staff involved (not names, e.g 2 embryologists) and dates. See additional notes for OHSS incidents)	
Number of eggs collected (if applicable)	
Pregnancy outcome (Include if the patient returned a positive test and is the pregnancy is ongoing)	

Patient outcome	
Analysis of causes and or contributing factors to the incident. (This must include any corrective action that was recommended.)	
Date of conclusion of the event	
The total number of days the patient was hospitalised. (Multiple re-admissions must be recorded separately and include a total)	
OHSS reporting only (The following extra information is requested if the event is OHSS) 1) Type of stimulation (Agonist, Antagonist, Clomid) 2) Drug and dose used to induce ovulation 3) E2 level before the trigger 4) Paracentesis (Y/N) 5) Embryo Transfer (Y/N) 6) Pregnancy (Y/N).	
Attached documentation (indicate if extra documentation has been included in the submission.)	
Member of Key Personnel reviewing the case, and date of the review	

Return to:

FSANZ Secretariat, Waldron Smith Management, 119 Buckhurst Street, South Melbourne VIC 3205 (e-mail: kimo@wsm.com.au)