Australian Commission on **Safety and Quality** in Health Care

National Safety and Quality Standards for Assisted Reproductive Technology Services

Second Consultation Paper

November 2026

safetyandquality.gov.au

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Part A:
Consultation overview

Part A: Consultation overview

The Australian Commission on Safety and Quality in Healthcare (the Commission) has developed draft National Safety and Quality Standards for Assisted Reproductive Technology (ART) services. The Commission is conducting public consultation to seek feedback from sector stakeholders as well as those with lived experience in using ART services.

Independent accreditation and standards for ART services

In September 2025, Health Ministers announced broad scale reform for the ART sector following a rapid review of regulation and accreditation. The intent of this reform was to improve patient safety and quality of care, strengthen regulation and oversight, support informed consent and transparency, and provide clearer and more consistent services.

The Commission has a legislated responsibility for developing standards related to health care safety and quality matters and formulating national schemes that provide for accreditation of organisations.

National Safety and Quality Standards

The Commission develops standards and accreditation schemes for other health care organisations such as hospitals and day procedure centres, primary healthcare organisations and cosmetic surgery services.

As part of the reform, the Commission has been tasked to develop independent accreditation and standards for ART providers.

The Fertility Society of Australia and New Zealand's Reproductive Technology Accreditation Committee (RTAC) is currently responsible for developing standards and overseeing accreditation, however this responsibility will transfer to the Commission from December 2028.

First Consultation Paper

The Commission was engaged in April 2026 to undertake work on the Standards. Between August and September 2026 over 100 survey responses and 20 written submissions were received, in response to a public consultation on the draft National Safety and Quality Standards for Assisted Reproductive Technology Services (the Standards).

Refinements have been made to the Standards and will be tested by ART service providers in 2027, to determine acceptability and where further implementation resources are required. See **Next Steps** for further information.

This Consultation Paper

The draft Standards included appendices to support the Standards, which are now included in this Consultation Paper for public feedback. The Consultation Paper is structured in 3 parts:

- **Part A** - Consultation overview
- **Part B** - Consultation focus areas
- **Part C** - Consultation questions

The Commission is seeking feedback on the content of **Part B** through a survey. Part A and Part C are provided for context.

Public consultation seeking feedback

The public consultation survey is open for five weeks between **16 November 2026 to 18 December 2026**.

You can complete the survey via: **Assisted Reproductive Technology Standards - Public Consultation**

Next Steps

Piloting the Standards

Refinements from the first public consultation have been made to the draft Standards. To determine acceptability by the sector, a pilot of the Standards will be undertaken by Australian ART service providers.

The pilot will commence in 2027 and be used to:

- further refine the Standards
- determine whether additional implementation resources are required for the sector to meet the updated requirements.

Expressions of interest for the pilot

The Commission has received a number of expressions of interest to participate in the pilot.

If you represent an ART service provider, and have not already expressed an interest in participating, please contact the Commission for further information.

Transition plan

A transition plan will be developed in 2027 and undergo public consultation. The transition plan will include information on when ART service providers will be assessed to the new Standards, in the lead up to RTAC's role ceasing as the body responsible for accreditation in December 2028.

Feedback on the transition plan will also be used to refine the Assessment Framework, which will include the information about the frequency of assessments, reporting requirements and other arrangements to achieve and maintain accreditation.

Accreditation agencies

The Commission will undertake an approval process for accrediting agencies who wish to assess against the Standards. This process will be undertaken following the development of the accreditation scheme for the Standards.

Implementation resources

Throughout 2027 and 2028, the Commission will identify and develop resources to support implementation of the Standards. The Commission's ART Industry Advisory Group will support this work and will use feedback from the piloting of the Standards to support the prioritisation of resource development.

Further information

For more information on the Commission's role in standards and accreditation, please visit the Commission's website.

Sign up to receive further updates from the Commission on the development of standards and accreditation for ART: www.safetyandquality.gov.au/Subscribe

Part B:
Consultation focus areas

Part B: Consultation focus areas

This consultation paper focuses on the areas of feedback not sought in the first public consultation on the Standards conducted in August and September 2026.

The consultation focus areas are split into four sections:

- **Section 1** - Workforce requirements for ART service providers
- **Section 2** - Safety and quality reporting for ART service providers
- **Section 3** - Guidance on minimising multiple pregnancies
- **Section 4** - Improving outcomes for Aboriginal and Torres Strait Islander peoples accessing ART services

Section 1: Workforce requirements for ART service providers

CONSULTATION NOTES FOR SECTION 1

What does this section address in the safety and quality of ART?

This section addresses the workforce requirements for ART service providers accredited under the Standards. The requirements aim to support consistent qualifications, roles and responsibilities of the workforce.

How do these requirements link with the Standards?

The requirements outlined in this section sit separate to the Standards to allow them to be updated more frequently as evidence, trends or risks emerge. The Standards link with these requirements illustrated in **Figure 1**.

Figure 1 Excerpt from the draft Standards that link this section to the Standards

Item	Action
Workforce requirements	A05 The ART service provider: a. Maintains a workforce that can safely deliver its scope of services and is aligned with the Australian ART Workforce Requirements b. Monitors the workload of the workforce to support its scope of services being safe and high-quality c. Regularly assesses workforce competency and performance d. Monitors and improves the effectiveness of its credentialing process

Note: Figure 1 illustrates the draft Standards from the August 2026 Public Consultation Paper. The action number and description may be updated in a future version of the Standards.

Was this previously addressed in the RTAC Code of Practice?

Partially. The RTAC Code of Practice addressed the requirements of senior roles described as key personnel (sections 2.4 and 2.5). The Consultation Paper seeks feedback on whether further requirements should be put in place for the workforce.

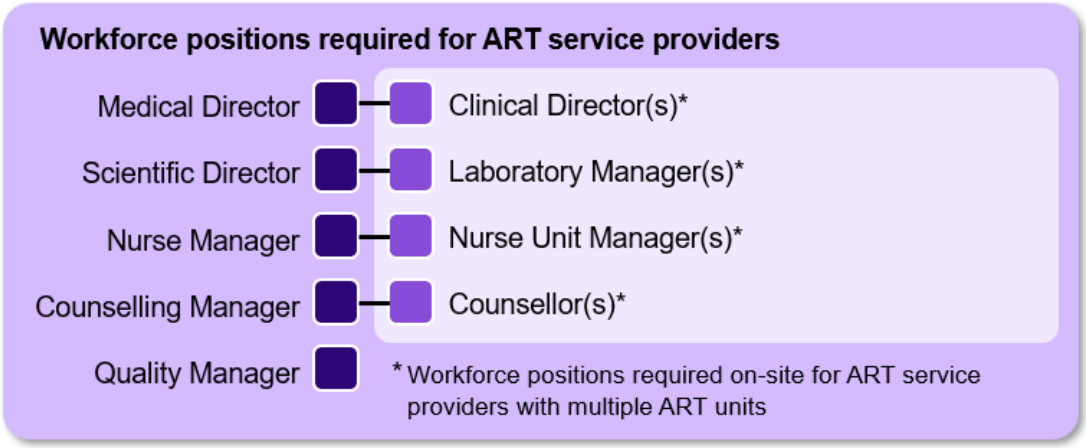
Consultation focus: Are the current workforce requirements fit for purpose?

All ART service providers must have the appropriately qualified workforce appointed to a key personnel position that has ultimate responsibility for:

- medical governance, overseen by a Medical Director
- scientific governance, overseen by a Scientific Director
- nursing governance, overseen by a Nurse Manager
- psychosocial governance, overseen by a Counselling Manager
- quality management, overseen by a Quality Manager.

Some ART service providers operate out of multiple clinics. Where a key personnel position is not available on-site, an appropriately qualified delegate must be appointed to undertake the governance and management functions of that key personnel position at each clinic. **Figure 2** illustrates the minimum workforce positions for ART service providers operating multiple ART units.

Figure 2 Minimum workforce positions required for ART service providers



The workforce positions described in this paper are the positions that require national qualifications, experience and other pre-requisites. Other roles exist within the ART workforce that are not defined by this work and are instead left to the ART service provider to ensure the appropriate workforce approach is taken. This would apply for roles in donor program management, administration etc.

The following minimum requirements are expected to be used across the ART workforce; however, ART service providers may choose to describe the role title in different ways.

The responsibilities, pre-requisites and professional recognition (where relevant) must be included to recruit new positions. Additional considerations are listed to support ART service providers understand other things they may seek to include in their recruitment activities, such as eligibility for membership of their professional association.

The ongoing requirements are expectations that ART service providers should be ensuring are undertaken annually by their employees and as expectations placed on contracted providers.

Minimum requirements for medical governance responsibilities

MEDICAL DIRECTOR

Responsibilities:	Clinical governance and management for all services provided by the ART service provider. Responsible for the clinical workforce providing services across the ART service. This includes the training, competency and supervision of clinical employees.
Pre-requisite requirements:	Certified Reproductive Endocrinology and Infertility (CREI) qualification, or A minimum of five years of experience in a Medical Director role
Professional recognition:	Fellowship of Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), or Fellowship of Royal Australasian College of Physicians (RACP), or Equivalent qualification recognised by the Medical Board of Australia (Medical Board) **[New]**
Ongoing requirements:	Minimum of 50% of the required Continued Medical Education (CME) hours per year spent on reproductive medicine and fertility **[New]** Maintain registration with the Medical Board
Additional considerations:	Eligibility for membership of the Fertility Society of Australia and New Zealand (FSANZ)

CLINICAL DIRECTOR

Responsibilities:	Clinical governance and management for the services provided at the ART unit for which they are responsible. They are required on-site or accessible during the hours of operation.
Pre-requisite requirements:	CREI qualification, or Currently undertaking the CREI and with ART service provider governance experience including in the case management of fertility **[New]**, or A minimum of two years of experience in a Clinical Director or Medical Director role or an equivalent leadership role with demonstrated responsibility for clinical governance **[New]**
Professional recognition:	Fellowship of RANZCOG, or Fellowship of RACP, or Equivalent qualification recognised by the Medical Board **[New]**
Ongoing requirements:	Minimum of 50% of the required CME hours per year spent on reproductive medicine and fertility **[New]** Maintain registration with the Medical Board
Additional considerations:	Eligibility for membership of FSANZ

Minimum requirements for scientific governance responsibilities

SCIENTIFIC DIRECTOR

Responsibilities:	Scientific governance and management for all services provided by the ART service provider. Responsible for the scientific workforce across the ART service. This includes the training, competency and supervision of scientific employees, technicians and trainees.
Pre-requisite requirements:	A minimum of 4 years of experience in an accredited ART laboratory, and A minimum of 2 years of experience in a managerial or supervisory role, and Previous experience in the management of a clinical embryology or clinical andrology laboratory
Educational requirements:	Doctorate (PhD) from an accredited institution in reproductive biology, or Masters (MSc) from an accredited institution in physiology of reproduction, cell biology and biochemistry with experience in experimental design, statistics and problem solving
Ongoing requirements:	20 hours of CPD per year spent on laboratory requirements, processes and quality control **[New]**
Additional considerations:	Australian Council for Certification of the Medical Laboratory Scientific Workforce (CMLS) Eligibility for membership of the FSANZ Scientists in Reproductive Technology (SIRT)

LABORATORY MANAGER

Responsibilities:	Scientific governance and management for the services provided at the ART unit for which they are responsible. They are required on-site or accessible during the hours of operation.
Pre-requisite requirements:	A minimum of 2 years of experience in an accredited ART laboratory
Educational requirements:	Masters (MSc) or Postgraduate diploma in physiology of reproduction, cell biology and biochemistry with experience in experimental design, statistics and problem solving
Ongoing requirements:	20 hours of CPD per year spent on laboratory requirements, processes and quality control **[New]**
Additional considerations:	Australian Council for Certification of the Medical Laboratory Scientific Workforce (CMLS) Eligibility for membership of SIRT

Minimum requirements for nurse governance responsibilities

NURSE MANAGER

Responsibilities:	Nursing governance and management for all services provided by the ART service provider. Responsible for the nursing workforce across the ART service. This includes the training, competency and supervision of nursing employees.
Pre-requisite requirements:	A minimum of 3 years of experience in the case management of fertility, and A minimum of 2 years of experience in a managerial or supervisory role **[New]**
Ongoing requirements:	10 hours of CPD per year spent on fertility **[New]** Maintain registration with the Nursing and Midwifery Board of Australia (Nursing and Midwifery Board)
Additional considerations:	Eligibility for membership of the FSANZ Fertility Nurses of Australasia (FNA)

NURSE UNIT MANAGER

Responsibilities:	Nursing governance and management for the services provided at the ART unit for which they are responsible. They are required on-site or accessible during the hours of operation.
Pre-requisite requirements:	A minimum of 2 years of experience in the case management of fertility, and A minimum of 1 year of experience in a managerial or supervisory role **[New]**
Ongoing requirements:	10 hours of CPD per year spent on fertility **[New]** Maintain registration with the Nursing and Midwifery Board
Additional considerations:	Eligibility for membership of FNA

Minimum requirements for psychosocial governance responsibilities

COUNSELLING MANAGER

Responsibilities:	Counselling governance and management for all services provided by the ART service provider. Responsible for the counselling workforce across the ART service. This includes the training, competency and supervision of counsellor employees.
Pre-requisites:	A minimum of 2 years of experience in fertility counselling A minimum of 50 hours of experience in donor conception and surrogacy **[New]**
Educational requirements:	A degree in a relevant field to psychological, psychosocial and therapeutic counselling **[New]**
Ongoing requirements:	10 hours of CPD per year spent on fertility counselling 2 hours of CPD per year spent on donor conception or surrogacy **[New]**
Additional considerations:	Eligibility for membership of the FSANZ Australian and New Zealand Infertility Counsellors Association (ANZICA)

COUNSELLOR

Responsibilities:	Responsible for counselling across the ART unit.
Pre-requisites:	A minimum of 200 hours of experience 10 hours of supervision from a Counselling Manager or Counsellor **[New]**
Educational requirements:	A degree in psychology, psychosocial or therapeutic counselling **[New]**
Ongoing requirements:	10 hours of CPD per year spent on fertility counselling 2 hours of CPD per year spent on donor conception or surrogacy **[New]**
Additional considerations:	Eligibility for membership of the ANZICA

Minimum requirements for quality management responsibilities

QUALITY MANAGER

Responsibilities:	Ongoing maintenance and coordination of the quality management and quality improvement systems across the workforce.
Pre-requisites:	A minimum of 2 years of experience in quality management
Educational requirements:	A degree in a relevant field in health sciences or quality management **[New]**
Ongoing requirements:	10 hours of CPD spent on quality improvement methodology, best-practice in ART or change management **[New]**

The Commission is seeking feedback on the minimum requirements for the workforce with management and governance responsibilities (see **Consultation Questions 1.1–1.5**). When considering feedback, the Commission is interested in understanding whether:

- the **description of responsibilities** is clear or requires further specification
- the **qualification and experience pre-requisites** are sufficient to address the description of responsibilities
- the **ongoing requirements** for the number of CME or CPD hours are set at a reasonable and effective number to support contemporary best-practice
- there are further **additional considerations** for ART service providers to consider with these roles.

Consultation Question 1.1

Are there further considerations for the responsibilities, pre-requisite requirements, professional recognition and ongoing requirements for **Medical Directors** and **Clinical Directors**?

Consultation Question 1.2

Are there further considerations for the responsibilities, pre-requisite requirements, educational requirements, ongoing requirements and additional considerations for **Scientific Directors** and **Laboratory Managers**?

Consultation Question 1.3

Are there further considerations for the responsibilities, pre-requisite requirements and ongoing requirements for **Nurse Managers** and **Nurse Unit Managers**?

Consultation Question 1.4

Are there further considerations for the responsibilities, pre-requisite requirements, educational requirements and professional development requirements for **Counselling Managers** and **Counsellors**?

Consultation Question 1.5

Are there further considerations for the responsibilities, pre-requisite requirements, educational requirements and professional development requirements for **Quality Managers**?

Changes made to the workforce requirements create difficulties, if required immediately without a transition period and will therefore be subject to grandfathering. That is, an exception for people currently employed in these key personnel positions to meet the additional requirements in this consultation paper. For these members of the workforce, the workforce requirements of the 2025 RTAC Code of Practice would be in place for a defined period of time.

Consultation Question 1.6

Are there considerations for grandfathering the workforce requirements outlined for key personnel? What is a reasonable amount of time to expect these requirements to be in place for all members of the workforce? Should ART service providers be required to have a plan in place for those under the grandfathering exception?

Consultation focus: Is there support to define the credentialing for professions not under the NRAS?

Some professions within the ART sector are regulated under the National Registration and Accreditation Scheme (NRAS) administered by the Australian Health Practitioner Regulation Agency (Ahpra) and a relevant National Board. For example:

- Fertility specialist doctors are regulated by the Medical Board
- Fertility nurses are regulated by the Nursing and Midwifery Board.

However certain professions in the ART sector that directly treat or manage consumers are not regulated under the NRAS, including:

- Clinical embryologists
- Fertility counsellors.

The Commission has developed guidance on credentialing and defining scope of practice for clinicians, which outlines the process of credentialing, defining a scope of practice and re-credentialing.

Credentialing

Credentialing is the process used to verify that an individual has the qualifications, experience, registration, competencies and professional standing required to perform their role. Credentialing should occur before an individual commences their duties.

The process of credentialing should verify:

- qualifications
- registration or professional standing (where applicable)
- relevant training
- experience
- competence
- professional development activities
- any restrictions on practice.

Scope of practice

A documented scope of practice is required for workforce members.

Developing the scope of practice should include:

- the individual's qualifications and competence
- organisational capability
- available resources and infrastructure
- patient safety considerations
- service requirements.

Re-credentialing

Periodic reviews of workforce credentials and scope of practice should be undertaken.

The process of re-credentialing should consider:

- ongoing professional standing
- maintenance of qualifications
- continuing professional development
- performance information
- competence and experience
- changes to roles, responsibilities or new restrictions on practice.

Consultation Question 1.7

Is there support for the Commission to develop national credentialing and scope of practice guidance for **clinical embryologists**? Which organisations, peak bodies or experts should be consulted to refine this guidance?

Consultation Question 1.8

Is there support for the Commission to develop national credentialing and scope of practice guidance for **fertility counsellors**? Which organisations, peak bodies or experts should be consulted to refine this guidance?

Consultation focus: What factors support safe and effective workforce levels in the ART sector?

Recent research[1] has indicated that lower staffing or workforce levels are associated with risks in ART laboratories. ART service providers are currently required to demonstrate a commitment to adequate staffing, training and ongoing education.

To support consistency across the ART sector, the Commission proposes to adopt a national approach to safe and effective workforce levels. Feedback from the August 2026 Consultation Paper on the draft Standards indicated that the Staffing Model for ART (*smART*) was considered to be an industry-accepted approach to tailoring adequate workforce levels for Australian ART service providers.

Components addressed by *smART*

- Complexity of procedures performed including with various components (for example, Intracytoplasmic Sperm Injection [ICSI] vs ICSI with Preimplantation Genetic Testing [PGT] vs ICSI using fresh Testicular Sperm Extraction [TESE])
- Number of procedures performed (for example, 100 cycles annually, based on a 350-day lab operations)
- Laboratory quality control tasks (for example, liquid nitrogen tank fills)
- Staffing structures, supervision requirements, qualifications and experience of workforce, leave entitlements and ongoing professional requirements
- Adjustments for small- and medium-sized laboratories.

Consultation Question 1.9

If the Commission adopted *smART* as the basis for nationally consistent staffing levels, what additional areas of content or guidance would support ART service providers that is not currently outlined by the *smART* calculators?

This work relates to the requirements outlined by Health Ministers in the development of workforce and staffing guidance. The final guidance for ART service providers will include:

- the evidence requirements that ART service providers must provide for review during assessments
- transition arrangements, including grandfathering requirements, that are appointed before December 2028 – the date when the Commission's Standards and accreditation scheme come into effect.

Consultation Question 1.10

Are there additional considerations that would support ART service providers address issues around workforce and staffing?

[1] Lee, YSL et al. 2023 Guidelines for Best Practice for Staffing of ART Laboratories and Professional Development of IVF Scientists, Fertility and Reproduction, Vol. 05, No. 03, pp163-175, https://doi.org/10.1142/S2661318223500160

Section 2: Safety and quality reporting for ART service providers

CONSULTATION NOTES FOR SECTION 2

What does this section address in the safety and quality of ART?

This section addresses the reporting requirements for ART service providers. The requirements aim to support transparency on safety and quality events occurring within the ART sector to support a better understanding of safety and quality improvements.

How do these requirements link with the Standards?

The requirements outlined in this section sit separate to the Standards to allow them to be updated more frequently as evidence, trends or risks emerge. The Standards link with these requirements illustrated in **Figure 3**.

Figure 3 Excerpt from the draft Standards that link this section to the Standards

Item	Action
Reporting adverse events	A26 The ART service provider: a. Reports all serious adverse events according to the Requirements for adverse event reporting for ART services b. Reviews and categorises all serious adverse events c. Acts to reduce recurrences of all serious adverse events

Note: Figure 3 illustrates the draft Standards from the August 2026 Public Consultation Paper. The action number and description may be updated in a future version of the Standards.

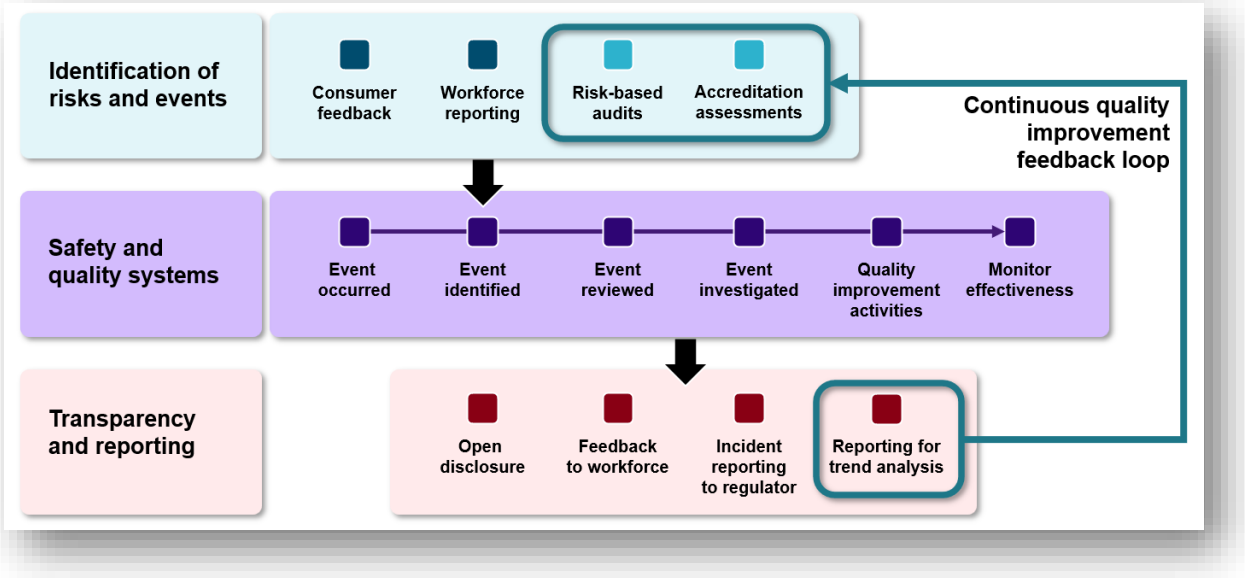
Was this previously addressed in the RTAC Code of Practice?

Partially. The RTAC Code of Practice addressed the adverse event reporting (section 4.2 and Attachment 1). The Consultation Paper seeks feedback on whether to expand this reporting to include other types of events such as near misses.

Consultation focus: Would a broader approach to safety and quality reporting support improvements across the sector?

Transparency and reporting are key areas of safety and quality that enable improvements at both the service-level and the system-level. Effective safety and quality systems can support the identification of risks and events that threaten high-quality ART services. **Figure 4** illustrates the relationship between service-level trend reporting and system-level insights.

Figure 4 Continuous quality improvement feedback loop from service-level reporting.



The categories of information currently reported by ART service providers includes:

- **consumer outcomes** – this information includes things like pregnancy success rates and is reported to a clinical quality registry; this information is published at the service-level on the YourIVFSuccess.com.au website that supports consumer choice
- **accreditation outcomes** – this information includes things like non-conformities following accreditation assessments and is reported to the Reproductive Technology Accreditation Committee (RTAC) and to ART regulators; this information is summarised in annual reporting from RTAC but includes only limited details to support wider improvements
- **adverse events** – this includes things like infections following egg pick-ups and is reported to the RTAC and to ART regulators; this information is summarised in annual reporting from RTAC but includes only limited details to support wider improvements.

The reporting requirements for adverse events are categorised into six types of events that are required to be reported. However, the types of adverse events focus heavily on the medical or surgical conditions arising from ART procedures, instead of the broader types of events that encompass the other areas of receiving care from an ART service provider.

To better support service providers, the workforce and regulators to understand the risks and trends, the Commission proposes expanding the current categories of reporting. This may include:

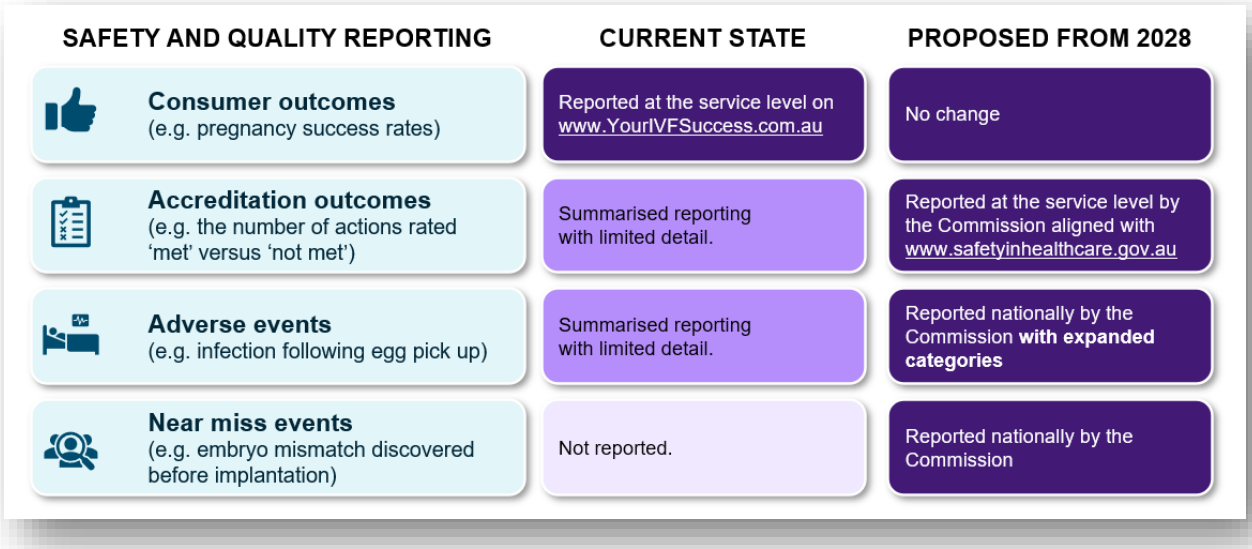
- a **broader range of safety and quality events** – this would cover additional reporting categories that describe the broader multi-disciplinary elements of ART service provision, such as events from medical, scientific, nursing and allied health interventions
- **near miss events** – these are events where a breakdown or gap in safety and quality systems that may not result in harm but do indicate an opportunity for quality improvement.

Reporting for ART service providers is restricted to serious adverse events which:

- results or may result in the transmission of a communicable disease
- results in a breach of legislation
- arises from a gamete or embryo identification mix up
- causes a loss of viability of gametes or embryos or suspected deterioration (beyond the ART unit's documented accepted laboratory standards) that renders them unsuitable for use
- 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
- causes specific medical or surgical conditions, including the following conditions with certain requirements, following ART procedures (for example, ovarian hyperstimulation syndrome (OHSS), confirmed pelvic infection, complication at oocyte retrieval, ovarian torsion, complication of a surgical sperm retrieval procedure, other serious medical or surgical condition resulting directly from ART treatment requiring hospitalisation, severe mental health event, death).

A broader approach to safety and quality reporting for the ART sector is illustrated in **Figure 5**. The Commission is seeking feedback on the proposed approach.

Figure 5 Proposed enhancements to safety and quality reporting to support system-level insights.



Consultation Question 2.1

What types and examples of adverse events and near miss events would be valuable to capture for trend analysis and greater system-level insights?

Consultation Question 2.2

What mechanisms could support a better culture for workforce reporting?

Consultation focus: What is the appropriate reporting period for trend analysis to support system-level insights?

ART service providers have current reporting requirements[2] that include information on the types and occurrences of events along with descriptive details around investigation into the events. These reporting requirements group serious incident reporting requirements with those that support trend analysis to respond to issues affecting all ART service providers.

The Commission proposes to refine the reporting requirements that support trend analysis, separate to the serious incident reporting requirements that support ART regulators to understand the details of specific incidents and take appropriate action.

Safety and quality trend analysis in the ART sector is supported by a minimum amount of information submitted from ART service providers. The Commission is seeking feedback on the information for public reporting that would support system-level learning from trends.

Information that may support system-level insights for the ART sector:

- safety and quality event
- type of procedure, if relevant (for example, IVF, ICSI)
- relevant dates (for example, date of event, date of identification/notification)
- source of identification (for example, workforce, internal audit, consumer, accreditation assessment).

The quality of data reporting is an important factor to consider when putting together reporting requirements. The existing adverse event reporting requirements have approximately 30 fields to complete and are required within a short period of time. To balance the benefits of timely data reporting with the requirements to keep the data high-quality, the Commission is seeking feedback on quarterly consolidated data submissions from ART service providers.

It is important to note that ART regulators also have reporting requirements that support their approach to the licensing to operate within their jurisdiction. These reporting requirements remain the responsibility of ART regulators and may be more frequent for example, serious incident notifications and response planning.

Consultation Question 2.3

Noting that the frequency of reporting requirements needs to balance timeliness with the quality of data, are there concerns about moving to a quarterly data report of safety and quality events?

[2] Fertility Society of Australia and New Zealand, RTAC Code of Practice Attachment 1, www.fertilitysociety.com.au/art-regulation/rtac-codes-of-practice

Consultation focus: How can consumers be better supported to understand safety and quality reporting?

It is important that consumers understand and interpret data. The changes to information proposed in this Consultation Paper will provide more publicly accessible information for consumers.

The Commission is interested in balancing the transparency that reporting of broader safety and quality events will bring, with the right amount of guidance to support consumers to derive insights, rather than be overwhelmed with information.

Consultation Question 2.4

What information would support consumers to understand the safety and quality events reported? Are there good examples from other fields or internationally that the Commission could emulate to support consumer insight?

Section 3: Guidance on minimising multiple pregnancies

CONSULTATION NOTES FOR SECTION 3

What does this section address in the safety and quality of ART?

This section addresses the reduction of avoidable risk related to multiple pregnancies. Multiple pregnancies is a recognised risk associated with ART services and remains an important consideration for consumers, clinicians and service providers.

Compared with single pregnancies, multiple pregnancies are associated with increased complexity of care and a higher risk of adverse outcomes. Although rates of multiple pregnancy have declined over time through evolutions in clinical practice, including greater use of single embryo transfer, minimising avoidable multiple pregnancies remains an important component of high-quality ART care.

How do these requirements link with the Standards?

The requirements are referred to in the Standards, illustrated in **Figure 6**, but the Commission seeks feedback on whether Guidelines should be integrated into the Standards or as a standalone document.

Figure 6 Excerpt from the draft Standards that link this section to the Standards

Item	Action
Minimising multiple pregnancies	A15 The ART service provider minimises the incidence of multiple pregnancies aligned with the Guidelines on minimising incidence of multiple pregnancies

Note: Figure 6 illustrates the draft Standards from the August 2026 Public Consultation Paper. The action number and description may be updated in a future version of the Standards.

Was this previously addressed in the RTAC Code of Practice?

Yes. The RTAC Code of Practice addressed the requirements to minimise multiple pregnancies (sections 4.3). The Consultation Paper seeks feedback on whether this advice requires updating.

Consultation focus: Is the guidance on minimising incidence of multiple pregnancies fit-for-purpose?

The Guidelines describe the conditions required to minimise the incidence of multiple pregnancies related to embryo transfer requirements. This guidance from the RTAC Code of Practice has been reformatted to focus on the conditions of when single embryo and multiple embryo transfers are required.

Guidance on minimising multiple pregnancies

Single embryo transfer – 1 embryo or oocyte transferred

Single embryo or oocyte transfer (no more than one embryo or oocyte) should be the standard practice to minimise the risk of multiple pregnancies.

Multiple embryo transfer – 2 embryos or oocytes transferred

Multiple embryo transfer should only be considered when the oocytes used to create the embryos were retrieved from a person over 35 years of age at the time of oocyte collection.

Currently this guidance does not include information about the exceptional circumstances in which a multiple embryo transfer of up to two embryos or oocytes transferred may be permitted. For example:

- treatment history involving a recurrent lack of successful transfers
- individual clinical circumstances that warrant a multiple embryo transfer.

Consultation Question 3.1

Are there additional circumstances where two embryos or oocytes may be transferred?

Consultation Question 3.2

What level of oversight or safeguards (for example, case discussion and decision across Medical and Scientific Director) would support ART service providers in minimising the incidence of multiple pregnancies?

Consultation focus: Should the guidance on minimising incidence of multiple pregnancies be standalone or embedded?

Requirements that involve specific detail can be either standalone or embedded in the Standards.

Requirements that are referenced as a standalone piece of guidance are linked in the text of the action. These requirements may be updated more frequently or are already contextualised as a resource that exists in its own right. An example of a standalone approach is illustrated in **Figure 7,** which references the document (i.e. the Australian Open Disclosure Framework).

Figure 7 Example of standalone guidance

Item	Action
Incident management and open disclosure	1.06 The ART service provider uses the Australian Open Disclosure Framework when a consumer or donor conceived person is harmed through the delivery of its services

Requirements that are embedded give the detail required in the text of the action. These requirements are unlikely to change and would need to wait for a new edition of the Standards before they are updated.

An example of an embedded approach is illustrated in **Figure 8,** which describes the number of identifiers to be used (i.e. three identifiers).

Figure 8 Example of embedded guidance

Item	Action
Processes for effective communication	3.25 The ART service provider has processes that use at least three identifiers to ensure consumers are correctly identified

In addition to the frequency of the guidance being updated, the use of embedded and standalone guidance may differ based on the complexity of the guidance:

- Standalone is preferred when the guidance is more complex or requires further references. This also offers opportunities where information in the guidance could further contextualise the reason why the requirements exist. For instance, the rationale behind single embryo transfers for all surrogacy cases or euploid embryos.
- Embedded guidance is preferred when the guidance is less complex.

In the box below, options one and two are provided as examples of what the standalone and embedded approaches may look like when applied to minimising multiple pregnancies.

Option one: Minimising multiple pregnancies [Standalone]

A15 The ART service provider minimises the incidence of multiple pregnancies aligned with the Guidelines on minimising incidence of multiple pregnancies.

[Consultation note: Guidance to be published separately but linked in Standards].

Option two: Minimising multiple pregnancies [Embedded]

A15 The ART service provider minimises the incidence of multiple pregnancies by ensuring only single embryo transfer is utilised. Multiple embryo transfer is only permitted with two embryos transferred in one of the following documented exceptions and confirmed with the ART service provider's Scientific Director:

a. treatment history involving a recurrent lack of successful transfers
b. individual clinical circumstances that warrant a multiple embryo transfer.

Consultation Question 3.3

Noting the full guidance is yet to be confirmed and may have additional complexity and references, what option is preferable for the guidance on minimising multiple pregnancies – Standalone or Embedded?

Section 4: Improving outcomes for Aboriginal and Torres Strait Islander peoples accessing ART services

CONSULTATION NOTES FOR SECTION 4

What does this section address in the safety and quality of ART?

The Standards require ART service providers to address the needs and preferences for all consumers.

Additional actions in the Standards address the structural inequities placed upon Aboriginal and Torres Strait Islander peoples. It is anticipated that these additional actions will improve overall outcomes and access of ART services.

How do these requirements link with the Standards?

The requirements are directly described in the Standards, illustrated in **Figure 9**.

Figure 9 Excerpt from the draft Standards that link this section to the Standards

Item	Action
Consumer populations and social determinants of health	1.09 The ART service provider identifies consumer populations using its service at greater risk of avoidable differences in health outcomes, including: a. People of Aboriginal and Torres Strait Islander origin b. People with disability c. People with diverse backgrounds, sexualities, relationship status and parenting arrangements
Safety and quality training	1.16 The ART service provider supports its workforce to provide culturally safe services to meet the needs of its Aboriginal and Torres Strait Islander consumers
Safe environment	1.25 The ART service provider provides a culturally safe environment that recognises the importance of the cultural beliefs and practices of Aboriginal and Torres Strait Islander people
Planning and delivering comprehensive care	3.22 The ART service provider has processes to: a. Routinely ask if a consumer is of Aboriginal and Torres Strait Islander origin b. Record this information in the consumer's healthcare record c. Use this information to optimise the planning and delivery of its services

Note: Figure 9 illustrates the draft Standards from the August 2026 Public Consultation Paper. The action number and description may be updated in a future version of the Standards.

Was this previously addressed in the RTAC Code of Practice?

No. The Consultation Paper seeks feedback on whether these actions would support better access and outcomes for Aboriginal and Torres Strait Islander peoples.

Consultation focus: Are the actions for Aboriginal and Torres Strait Islander peoples sufficient?

ART service providers are expected to create and maintain processes and environments that are culturally safe, respectful and responsive to the needs of Aboriginal and Torres Strait Islander peoples. These processes should include educating their workforce on what culturally safe care looks like.

Actions for Aboriginal and Torres Strait Islander peoples

- Consumer populations and social determinants of health (Action 1.09)
- Safety and quality training (Action 1.16)
- Safe environment (Action 1.25)
- Planning and delivering comprehensive care (Action 3.22)

Consultation Question 4.1

Do the Standards need additional actions to support better outcomes for Aboriginal and Torres Strait Islander peoples accessing ART services?

Consultation focus: What areas do ART service providers need guidance to support Aboriginal and Torres Strait Islander consumers and those conceived through ART?

The Standards describe a number of actions that address the needs and preferences of consumers and those conceived through ART that may happen to be Aboriginal and Torres Strait Islander peoples. Some of these actions may require specific implementation guidance to support effective systems and processes.

For example, the draft Standards describe the requirement to maintain donor records. For Aboriginal and Torres Strait Islander donors this may mean collecting information about ancestry to support the donor conceived person understand more about their identity if something was to happen between the donation and the donor conceived person reaching the age where they can access information about their donor.

Other actions that describe consumers and people conceived through ART

- Governance, leadership and culture (Action 1.01)
- Feedback and Complaints Management (Actions 1.07 and 1.08)
- Healthcare records (Actions 1.11 and 1.12)
- Shared decisions and planning care (Action 2.05)
- Communication that supports effective partnerships (Action 2.06)
- Partnerships in the planning, design, monitoring, and evaluation of services (Action 2.08)
- Documentation, provision and access to medicines-related information (Actions 3.15 and 3.16)
- Health promotion and prevention (Action 3.20)
- Understanding consumer needs and preferences (Action A11)
- Information related to donors (Action A21)

Consultation Question 4.2

Is there specific guidance that could be developed to support ART service providers understand and address requirements for consumers and people conceived through ART that are Aboriginal and Torres Strait Islander peoples?

Part C:
Consultation questions

Part C: Consultation questions

Consultation questions from Part B are listed here to support organisations prepare responses, however the individuals and organisations wishing to respond to this Consultation Paper are encouraged to read the discussion points from Part B to understand the intent behind the consultation questions.

Additional questions are asked about the individual or organisation responding to this Consultation Paper, to support the Commission and its ART Industry Advisory Group navigate the personal and professional interests that may influence their responses. For this reason, only responses collected through the online survey will be accepted.

1. Workforce requirements for ART service providers

Consultation Question 1.1

Are there further considerations for the responsibilities, pre-requisite requirements, professional recognition and ongoing requirements for **Medical Directors** and **Clinical Directors**?

Consultation Question 1.2

Are there further considerations for the responsibilities, pre-requisite requirements, educational requirements, ongoing requirements and additional considerations for **Scientific Directors** and **Laboratory Managers**?

Consultation Question 1.3

Are there further considerations for the responsibilities, pre-requisite requirements and ongoing requirements for **Nurse Managers** and **Nurse Unit Managers**?

Consultation Question 1.4

Are there further considerations for the responsibilities, pre-requisite requirements, educational requirements and professional development requirements for **Counselling Managers** and **Counsellors**?

Consultation Question 1.5

Are there further considerations for the responsibilities, pre-requisite requirements, educational requirements and professional development requirements for **Quality Managers**?

Consultation Question 1.6

Are there considerations for grandfathering the workforce requirements outlined for key personnel? What is a reasonable amount of time to expect these requirements to be in place for all members of the workforce? Should ART service providers be required to have a plan in place for those under the grandfathering exception?

Consultation Question 1.7

Is there support for the Commission to develop national credentiallng and scope of practice guidance for **clinical embryologists**? Which organisations, peak bodies or experts should be consulted to refine this guidance?

Consultation Question 1.8

Is there support for the Commission to develop national credentialing and scope of practice guidance for **fertility counsellors**? Which organisations, peak bodies or experts should be consulted to refine this guidance?

Consultation Question 1.9

If the Commission adopted *smART* as the basis for nationally consistent staffing levels, what additional areas of content or guidance would support ART service providers that is not currently outlined by the *smART* calculators?

Consultation Question 1.10

Are there additional considerations that would support ART service providers address issues around workforce and staffing?

2. Safety and quality reporting for ART service providers

Consultation Question 2.1

What types and examples of adverse events and near miss events would be valuable to capture for trend analysis and greater system-level insights?

Consultation Question 2.2

What mechanisms could support a better culture for workforce reporting?

Consultation Question 2.3

Noting that the frequency of reporting requirements needs to balance timeliness with the quality of data, are there concerns about moving to a quarterly data report of safety and quality events?

Consultation Question 2.4

What information would support consumers understand the safety and quality events reported? Are there good examples from other fields or internationally that the Commission could emulate to support consumer insight?

3. Guidance on minimising multiple pregnancies

Consultation Question 3.1

Are there additional circumstances where 2 embryos or oocytes may be transferred?

Consultation Question 3.2

What level of oversight or safeguards (e.g. case discussion and decision across Medical and Scientific Director) would support ART service providers in minimising the incidence of multiple pregnancies?

Consultation Question 3.3

Noting the full guidance is yet to be confirmed and may have additional complexity and references, what option is preferable for the guidance on minimising multiple pregnancies – Standalone or Embedded?

4. Improving outcomes for Aboriginal and Torres Strait Islander peoples accessing ART services

Consultation Question 4.1

Do the Standards need additional actions to support better outcomes for Aboriginal and Torres Strait Islander peoples accessing ART services?

Consultation Question 4.2

Is there specific guidance that could be developed to support ART service providers understand and address requirements for consumers and people conceived through ART that are Aboriginal and Torres Strait Islander peoples?

See also Next Steps for more information following this public consultation.

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