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

National Safety and Quality Assisted Reproductive Technology Service Standards

Consultation Paper

August 2026

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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 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
- formulating national schemes that provide for accreditation of organisations.

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

National Safety and Quality Standards

The Commission develops National Safety and Quality Standards and accreditation schemes for health care organisations such as hospitals and day procedure centres, primary healthcare organisations, mental health services and cosmetic surgery services.

The current state and anticipated changes for standards and accreditation in Australian ART services is outlined in **Table 1**.

Table 1 Anticipated changes for the ART sector with new standards and accreditation.

Area	Current state	From December 2028
Standards for ART sector	RTAC Code of Practice	National Safety and Quality Standards for Assisted Reproductive Technology Services (the Standards)
Standards developer for the ART sector	RTAC	The Commission
Accreditation scheme for the ART sector	RTAC	The Commission
Regulator and licensing of ART services	State and territory regulators	Unchanged – see *Regulators and licensing of ART service providers*
Reporting to clinical quality registries	Reports to the Australian and New Zealand Assisted Reproduction Database	Unchanged – see *Reporting to clinical quality registries*

What is out of scope for the Commission in ART sector reform

The changes to standards and accreditation for ART services is part of wider reform for the sector. The Commission has been given a clearly defined role in the reform; areas that are out of scope for this consultation, and the broader work of the Commission, include the role of the regulators, any impact on clinical quality registries and the interim arrangements.

Regulators and licensing of ART service providers

State and territory regulators of ART service providers will continue to have responsibility to issue licenses per their regulatory frameworks.

The Commission supports the role of regulators by facilitating information about accreditation outcomes. The Commission will work with regulators to ensure that their licensing frameworks include the new standards and accreditation scheme.

Reporting to clinical quality registries

The Australian and New Zealand Assisted Reproduction Database (ANZARD) is a clinical quality registry comprising information on ART treatment cycles in Australia and New Zealand. The required information to submit data to ANZARD is governed by the University of New South Wales's National Perinatal Epidemiology and Statistics Unit.

The draft National Safety and Quality Standards for Assisted Reproductive Technology Services maintain the requirement to submit data to ANZARD.

Interim arrangements for ART service provider accreditation

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

Development of safety and quality standards for ART service providers

Standards describe the actions that health services are required to meet to deliver high-quality care. The process of accreditation provides assurances to regulators, the workforce and the people using services that the appropriate systems are in place at a point in time to support the delivery of high-quality care, through an independent assessment process.

The draft Standards were developed using the National Safety and Quality Primary and Community Healthcare Standards as a starting point to support consistency in the approach to clinical governance, partnering with consumers and clinical safety.

Additional requirements that relate to the specific safety and quality risks for ART service providers have been included in these National Safety and Quality Standards for Assisted Reproductive Technology Services. The specific ART requirements have been developed into the Assisted Reproductive Technology Module which has been informed by:

- the existing standards and accreditation for ART services including the *RTAC Code of Practice*, *RTAC Accreditation Scheme* and *Technical Bulletins*
- the final report on the *Rapid Review of Assisted Reproductive Technology and In Vitro Fertilisation Regulation and Accreditation in Australia*
- the Commission's work in other areas of reform such as the National Safety and Quality Cosmetic Surgery Standards
- over 30 key informant interviews with experts within the field and those with lived experience, and more than 50 submissions to an online survey for key safety and quality issues.

The Commission has set up the Assisted Reproductive Technology Industry Advisory Group (Advisory Group) to provide advice on the development of standards and accreditation for ART services in Australia.

The Advisory Group provides critical input to:

- the drafting of the National Safety and Quality Assisted Reproductive Technology Service Standards (the Standards), including reviewing feedback from public consultation
- the assessment framework for accreditation to the Standards
- a pilot program to determine refinements for the Standards
- identifying and developing implementation resources for ART service providers.

Public consultation on the Standards

This consultation paper is structured in 3 parts.

- **Part A:** Consultation overview
- **Part B:** National Safety and Quality Assisted Reproductive Technology Service Standards – Consultation draft
  Advisory on not applicable actions
  Glossary for the Standards
- **Part C**: Appendices to support the Standards

The Commission is **seeking feedback on Part B** through an online survey. Parts A (this section) and C are provided for context.

Public consultation seeking feedback on the Standards

The **public consultation survey** is open for four weeks between **10 August 2026 to 6 September 2026**.

Separate consultation on Accreditation

The Commission will undertake additional targeted consultation with regulators and key stakeholders to develop accreditation arrangements for the ART sector. Accreditation requirements to the National Safety and Quality Assisted Reproductive Technology Service Standards will be outlined in an assessment framework. This framework will include:

- the requirements for newly established units
- frequency and requirements of assessments (currently referred to as audits)
- requirements to maintain accreditation (including reporting requirements)
- assessor requirements
- accreditation outcomes reporting.

Next steps

Following consultation, the Advisory Group will support the Commission in reviewing feedback. The Commission will work with states and territories to ensure that the standards for the ART sector support effective regulation and drive high-quality care.

The Commission anticipates that a pilot of these draft standards will commence in early 2027, to ensure the Standards are fit for purpose and inform any refinements required for finalisation. Throughout 2027 and 2028, the Commission will develop resources to support ART services with implementation of the Standards and tools to support self-assessment.

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:
National Safety and Quality Assisted Reproductive Technology Service Standards – Consultation draft

Part B: National Safety and Quality Assisted Reproductive Technology Service Standards – Consultation draft

Structure of the Standards

Two sections are used to group the draft National Safety and Quality Standards for Assisted Reproductive Technology Services (the Standards).

- **Section 1**: Actions from the National Safety and Quality Primary and Community Healthcare Standards
- **Section 2:** Assisted Reproductive Technology Module.

Consultation Note

State and territory health authorities may require an ART service provider to meet the National Safety and Quality Health Service (NSQHS) Standards and does not have to meet Section 1 as there are equivalent concepts covered in the NSQHS Standards.

Scope of the Standards

The Standards address areas of safety and quality for ART service providers to support the delivery of high-quality ART services.

ART service providers deliver clinical treatments, counselling services and laboratory procedures for the assessment and preparation of human oocytes, sperm or embryos.

ART service providers may offer a range of services, including in vitro fertilisation (IVF), gamete intrafallopian transfer, intracytoplasmic sperm injection (ICSI), gamete and embryo cryopreservation, surgical sperm recovery, oocyte, sperm or embryo donation, embryo biopsy or non-invasive sampling for preimplantation genetic testing (PGT), gestational and traditional surrogacy, in vivo maturation (IVM), intrauterine insemination (IUI).

ART service providers operate facilities that include:

- **ART Units** - a facility that includes a laboratory involved in collecting, preparation, processing and storage of human gametes and embryos for therapeutic purposes
- **Satellite Units** – a facility that operates for fewer than 180 days per year and does not provide onsite storage for gametes and embryos, operating under the supervision of an ART Unit
- **Offsite storage facilities** – a specialist facility located separately from an ART Unit and used by the ART Unit for the storage of human gametes and embryos. An offsite storage facility is not a Satellite Unit.

ART service providers may also utilise independently operated andrology laboratories.

Consultation Note

Requirements for audits will be outlined in an assessment framework that will be developed to support accreditation to the Standards.

Terminology used in these standards

- The term **consumers** is broadly used to describe the people who use the services of an ART service provider. This includes the donors and recipients of specimens, and their partners where relevant.

- The term **people conceived through ART** include donor conceived people. Donor conceived people are specified separately from people conceived through ART where it is relevant for this population.

- The term **specimens** is broadly used to describe the biological materials collected, used and stored by an ART service provider. Where there are specific requirements around the types of specimens, these have been specified using the relevant terms.

- Where a standard refers to two concepts it means that the process should apply to both concepts, where relevant.

  For an example where it applies to both, action A13 on Reproductive education describes preconception advice for donors and recipients that would apply to **both** the donors and recipients.

- A **glossary of terms** has been developed to support the understanding of terms used in the Standards.

Section 1: Actions from the National Safety and Quality Primary and Community Healthcare Standards

Clinical Governance Standard

Governance, leadership and culture

The ART service provider sets up and uses clinical governance systems to improve the safety and quality of health care for consumers.

Item	Action
Governance, leadership and culture	1.01 The ART service provider: a. Has a culture of safety and quality improvement b. Partners with consumers and people conceived through ART c. Sets priorities and strategic directions for safe and high-quality services, and ensures that these are communicated effectively to the workforce d. Establishes and maintains a clinical governance framework e. Clearly defines the safety and quality roles, responsibilities and accountabilities of those governing the ART service provider, management and the workforce f. Monitors and reviews the safety and quality performance of the ART service provider g. Considers the safety and quality of health care for consumers and donor-conceived people in its business decision-making h. Establishes and maintains systems for integrating care with other service providers involved in a consumer's care

Consumer safety and quality systems

Safety and quality systems are integrated with governance processes to enable the ART service provider to actively manage and improve the safety and quality of its services for consumers.

Item	Action
Policies and procedures	1.02 The ART service provider uses a risk management approach to: a. Establish and maintain policies, procedures and protocols b. Make policies, procedures and protocols easily available to the workforce c. Monitor and take action to improve adherence to policies, procedures and protocols d. Ensure compliance with relevant safety and quality legislation, regulation and jurisdictional requirements
Measurement and quality improvement	1.03 The ART service provider uses a range of data to: a. Identify priorities for safety and quality improvement b. Implement and monitor safety and quality improvement activities c. Measure changes in safety and quality outcomes d. Provide timely information on safety and quality performance to consumers, people conceived through ART and the workforce
Risk management	1.04 The ART service provider: a. Supports the workforce to identify, mitigate and manage safety and quality risks b. Documents and routinely monitors safety and quality risks c. Plans for, and manages, ongoing service provision during internal and external emergencies and disasters.
Incident management and open disclosure	1.05 The ART service provider has an incident management system that: a. Supports the workforce to recognise and report incidents b. Supports consumers and people conceived through ART to communicate concerns or report incidents c. Involves the workforce in the review of incidents d. Provides timely feedback on the analysis of incidents to the workforce, consumers and people conceived through ART who have communicated concerns or incidents e. Uses the information from the analysis of incidents to improve safety and quality f. Incorporates risks identified in the analysis of incidents into the risk management system g. Regularly reviews and acts to improve the effectiveness of the incident management and investigation systems
	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

Item	Action
Feedback and complaints management	1.07 The ART service provider: a. Seeks feedback from consumers and people conceived through ART about their experiences and outcomes of its services b. Has processes to regularly seek feedback from the workforce on their understanding and use of the safety and quality system c. Uses feedback to improve safety and quality
	1.08 The ART service provider: a. Provides opportunities for its consumers and people conceived through ART to report complaints b. Has processes to address complaints in a timely way c. Uses information from the analysis of complaints to improve safety and quality
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
	1.10 The ART service provider uses information on its consumer populations to inform planning and delivery of its services
Healthcare records	1.11 The ART service provider has a healthcare record system that: a. Makes the healthcare record available to healthcare providers at the point of care b. Supports healthcare providers to maintain accurate and complete healthcare records c. Complies with privacy and security regulations d. Supports audits of healthcare records e. Facilitates a consumer's access to their healthcare record
	1.12 The ART service provider has processes to: a. Receive and review reports on consumers b. Recall consumers and communicate about reports and health care options c. Take action on reports in a timely manner d. Document reports in a consumer's healthcare record
	1.13 The ART service provider using My Health Record has processes to: a. Use national healthcare identifiers for consumers and healthcare providers b. Use standard national terminologies

Item	Action
	c. Support healthcare providers to use My Health Record to optimise the safety and quality of health care for consumers
	1.14 The ART service provider providing clinical information to the My Health Record system has processes to: a. Comply with legislative requirements b. Ensure the accuracy and completeness of information uploaded

Clinical performance and effectiveness

The workforce has the right qualifications, knowledge and skills to provide safe, high-quality health care to consumers.

Item	Action
Safety and quality training	1.15 The ART service provider: a. Provides its workforce with orientation and training to their safety and quality roles on commencement with the service, when safety and quality responsibilities change and when new services are introduced b. Identifies the training needs of its workforce to meet the requirements of these Standards c. Ensures its workforce completes training to meet its safety and quality training needs
	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
Safety and quality roles and responsibilities	1.17 The ART service provider has processes to support its workforce to understand and fulfil their assigned safety and quality roles and responsibilities
Evaluating performance	1.18 The ART service provider has valid and reliable review processes for the workforce that: a. Are used to regularly review their performance b. Identify needs for training and development of safety and quality

Item	Action
Scope of practice	1.19 The ART service provider has processes to ensure that its workforce has the qualifications, knowledge and skills required to perform their role by: a. Describing the scope of practice for its workforce delivering its services b. Monitoring healthcare providers' practices to ensure they are operating within their designated scope of practice c. Reviewing the workforces' scope of practice when a service, procedure or technology is introduced or substantially altered
Evidence-based care	1.20 The ART service provider: a. Provides its healthcare providers with ready access to best practice guidelines and available evidence, clinical care standards and decision support tools relevant to their clinical practice b. Supports its healthcare providers to use best practice guidelines and available evidence, clinical care standards and decision support tools relevant to their clinical practice to deliver best practice care
Variation in care delivered and health outcomes	1.21 The ART service provider supports its workforce to: a. Monitor and review care delivered against relevant best practice care b. Explores reasons for variation of health care from best practice c. Uses information on unwarranted variation from best practice to improve its services

Safe environment for the delivery of care

The environment in which services are delivered enables safe and high-quality health care for consumers.

Item	Action
Safe environment	1.22 The ART service provider maximises safety and quality of its services: a. Through the design of the environment, management of the location where its services are provided and educating the workforce on the effective use of process related to these environments b. By providing access to an environment, devices and equipment that are fit for purpose and well maintained c. By ensuring consumer's privacy in its environments
	1.23 The ART service provider identifies areas that have a high risk of unpredictable behaviours and develops strategies to minimise the risks of harm to consumers and the workforce

Item	Action
	1.24 The ART service provider supports consumers to access health care, including consumers from diverse backgrounds and consumers with disability
	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

Partnering with Consumers Standard

Clinical governance and quality improvement systems to support partnering with consumers

Systems are designed and used to support consumers to be partners in healthcare.

Item	Action
Integrating clinical governance	2.01 Healthcare providers use the safety and quality systems from the Clinical Governance Standard when: a. Implementing policies and procedures for partnering with consumers b. Managing risks associated with partnering with consumers c. Monitoring processes for partnering with consumers

Partnering with consumers in their own care

Partnering with consumers underpins the delivery of care. Consumers are partners in their own health care to the extent that they choose.

Item	Action
Healthcare rights and informed consent	2.02 The ART service provider: a. Uses a Charter of Rights consistent with the Australian Charter of Healthcare Rights b. Has processes to support the workforce to apply the principles of the Charter of Rights in the planning and delivery of health care c. Makes the Charter of Rights easily accessible for consumers and people conceived through ART d. Ensures its informed consent processes comply with legislation and best practice
	2.03 The ART service provider has processes to identify: a. The capacity of a consumer to make decisions about their own health care **Consultation note: The sub-action below is from the National Safety and Quality Standards Primary and Community Healthcare is not considered relevant to ART service providers.** b. A substitute decision-maker if a consumer does not have the capacity to make decisions for themselves

Item	Action
Shared decisions and planning care	**Consultation note: The action below is from the National Safety and Quality Standards Primary and Community Healthcare is not considered relevant to ART service providers.** 2.04 The ART service provider has processes for healthcare providers to partner with consumers and/or their substitute decision-maker to plan, communicate, set and review goals, make decisions and document their preferences about their current and future health care
	2.05 The ART service provider supports the workforce to form partnerships with consumers so that they can be actively involved in their own health care

Health literacy

ART service providers communicate with consumers in a way that supports effective partnerships.

Item	Action
Communication that supports effective partnerships	2.06 The workforce communicates with consumers and people conceived through ART about its services and their health in a way that: a. Is tailored to their needs and preferences b. Is easily understood c. Addresses the need for ongoing health care
Accessing healthcare service information	2.07 The ART service provider makes information available to consumers on: a. The services available b. The opening hours and how to access health care c. Who can access the services d. Estimated service costs e. Alternative health care when the service is closed, after-hours and in an emergency f. Service location(s) and access details g. Mechanisms for providing feedback and contact details for the appropriate healthcare complaints authority

Partnering with consumers in service design

Consumers are partners in the planning, design, monitoring and evaluation of services.

Item	Action
Partnerships in the planning, design, monitoring and evaluation of services	2.08 The ART service provider works in partnership with consumers and people conceived through ART to seek and incorporate their views and experiences into the planning, design, monitoring and evaluation of services

Clinical Safety Standard

Clinical governance and quality improvement to support clinical safety

The ART service provider uses its systems to support the workforce to address and mitigate clinical safety risks.

Item	Action
Integrating clinical governance	3.01 The workforce uses safety and quality systems from the Clinical Governance Standard when: a. Implementing policies and procedures for clinical safety b. Managing risks associated with clinical safety c. Identifying training requirements to support clinical safety
Applying quality improvement systems	3.02 The ART service provider applies the quality improvement system from the Clinical Governance Standard when: a. Monitoring clinical safety risks b. Implementing strategies to improve clinical safety outcomes and associated processes c. Reporting on clinical safety
Partnering with consumers	3.03 The workforce uses the ART service provider's processes from the Partnering with Consumers Standard when addressing clinical safety to: a. Actively involve consumers in their own health care b. Meet the consumer's information needs c. Share decision-making

Preventing and controlling infections

Evidence-based systems are used to prevent and control healthcare-associated infections. Consumers presenting with, or with risk factors for, infection or colonisation with an organism of local, national or global significance are identified promptly, and receive the necessary management and treatment. The ART service provider is clean and hygienic.

Item	Action
Standard and transmission-based precautions	3.04 The ART service provider has processes to apply standard and transmission-based precautions that are fit for the setting and consistent with the current edition of the *Australian Guidelines for the Prevention and Control of Infection in Healthcare*, jurisdictional requirements, and relevant jurisdictional laws and policies to screen and minimise infections for and between consumers and specimens.
Hand hygiene	3.05 The ART service provider has a hand hygiene process that is incorporated in its overarching infection prevention and control program as part of standard precautions and: a. Is consistent with the appropriate elements of the National Hand Hygiene Initiative, and jurisdictional requirements b. Supports the workforce and consumers to practise hand hygiene

Item	Action
Respiratory hygiene, cough etiquette and physical distancing	3.06 The ART service provider supports the workforce and consumers to practise respiratory hygiene, cough etiquette and physical distancing where relevant
Aseptic technique	3.07 Where aseptic technique is required as part of the provision of health care, the ART service provider has processes to: a. Identify procedures where aseptic technique applies b. Monitor healthcare providers' practices to ensure compliance with the ART service provider's policies and procedures on aseptic technique
Invasive medical devices	3.08 Where invasive medical devices are used, the ART service provider has processes for the appropriate use and management of invasive medical devices that are consistent with the current edition of the *Australian Guidelines for the Prevention and Control of Infection in Healthcare*
Clean and safe environment	3.09 The ART service provider has processes to maintain a clean, safe and hygienic environment – in line with the current edition of the *Australian Guidelines for the Prevention and Control of Infection in Healthcare*, and jurisdictional requirements – to: a. Respond to environment risks, including novel infections b. Require cleaning and disinfection using products listed on the Australian Register of Therapeutic Goods consistent with manufacturers' instructions for use and recommended frequencies c. Provide access to training on cleaning processes for routine and outbreak situations, and novel infections
	3.10 The ART service provider has processes to evaluate and respond to infection risks for: a. New and existing equipment, devices and products used in its services b. Clinical and non-clinical areas, and workplace amenity areas c. Maintaining, repairing and upgrading buildings, equipment, furnishings and fittings d. Handling, transporting and storage of linen e. Novel infections, and risks identified as part of a public health response or pandemic planning
Workforce screening and immunisation	3.11 The ART service provider has a risk-based workforce vaccine-preventable diseases screening and immunisation process that: a. Is consistent with the current edition of the *Australian Immunisation Handbook* b. Is consistent with jurisdictional requirements for vaccine-preventable diseases c. Identifies and addresses specific risks to the workforce and consumers

Item	Action
Infections in the workforce	3.12 The ART service provider has risk-based processes for preventing and managing infections in the workforce that: a. Are consistent with the relevant state or territory work health safety regulation and the current edition of the *Australian Guidelines for the Prevention and Control of Infection in Healthcare* b. Align with state and territory public health requirements for workforce screening and exclusion periods c. Manage risks to the workforce, consumers, visitors and contractors including for novel infections d. Promote non-attendance or remote-attendance at work and avoiding visiting or volunteering when infection is present or suspected e. Plan for, and manage, ongoing service provision during outbreaks and pandemic or events where there is increased risk of transmission of infection
Reprocessing of reusable medical devices	3.13 Where reusable equipment, instruments and devices are used, the ART service provider has: a. Processes for reprocessing that are consistent with relevant national and international standards, in conjunction with manufacturers' guidelines b. A process for critical equipment, instruments, and devices that is capable of identifying the – consumer – procedure – reusable equipment, instruments and devices that were used for the procedure c. Processes to plan and manage reprocessing requirements and additional controls for novel and emerging infections
Antimicrobial stewardship	3.14 The ART service provider that prescribes, supplies and/or administers antimicrobials: a. Provides healthcare providers with access to, and promotes the use of, current evidence-based Australian therapeutic guidelines and resources on antimicrobial prescribing b. Incorporates core elements, recommendations and principles from the current Antimicrobial Stewardship Clinical Care Standard into service delivery c. Supports healthcare providers who prescribe antimicrobials to review compliance of antimicrobial prescribing against current local or Australian therapeutic guidelines d. Supports healthcare providers to identify the areas of improvement and takes action to increase the appropriateness of antimicrobial usage e. Has mechanisms to educate consumers about the risks, benefits and alternatives to antimicrobials for their condition

Medication safety

Systems are in place to support the safe, appropriate and effective use of medicines, reduce the risks associated with medicine-related events and improve the safety and quality of medicine use.

Item	Action
Documentation, provision and access to medicines-related information	3.15 An ART service provider that prescribes, supplies and/or administers medicines has processes to ensure healthcare providers work within their scope of clinical practice to: a. Take a best possible medication history on presentation or as early as possible in the episode of care b. Ensure a consumer's medicines-related information is included in a consumer's healthcare record c. Partner with consumers in the management of their medicines d. Support consumers to maintain a current and accurate medicines list e. Encourage consumers to share their medicines list with other healthcare providers involved in their care and/or does so on a consumer's behalf with their consent f. Use information on a consumer's medication history to minimise risks in the planning and delivery of health care
	3.16 The ART service provider has processes to ensure healthcare providers work within their scope of clinical practice to: a. Provide information on medicines tailored to the consumer's needs and preferences b. Take action when the workforce or consumer identifies a suspected medicines-related problem c. Report suspected adverse drug reactions to the Therapeutic Goods Administration
Safe and secure storage and supply of medicines	3.17 An ART service provider that prescribes, stores, supplies and/or administers medicines complies with manufacturer's instructions, legislative and jurisdictional requirements for the: a. Safe and secure storage of medicines, including high-risk medicines b. Storage of temperature-sensitive medicines and cold chain management c. Supply of medicines d. Disposal of unused, unwanted or expired medicines
High-risk medicines	3.18 An ART service provider that prescribes, stores, supplies and/or administers medicines has processes to: a. Identify high-risk medicines within the service b. Safely store, prescribe, supply, administer and dispose of high-risk medicines

Comprehensive care

Comprehensive care is the coordinated delivery of the total health care required with regard for a consumer's preferences. It may be a discrete episode of care or part of an ongoing comprehensive care plan. This health care is planned and delivered in collaboration with the consumer. It considers the effect of the consumer's health issues on their life and wellbeing, and is clinically appropriate.

Item	Action
Multidisciplinary collaboration	3.19 The ART service provider: a. Collaborates with other healthcare providers involved in a consumer's care b. Supports collaboration with other care providers to develop a coordinated approach to the planning and delivery of health care c. Facilitates reporting to a consumer's other relevant care providers
Health promotion and prevention	3.20 The ART service provider has processes to support health education and promotion, illness prevention and early intervention for consumer, considering its consumer population
Planning and delivering comprehensive care	3.21 The ART service provider has processes to ensure healthcare providers work within their scope of practice to plan and deliver comprehensive care by: a. Conducting a risk screening and assessment b. Conducting a clinical assessment and diagnosis c. Identifying the consumer's goals of care d. Developing and agreeing a plan for care in partnership with the consumer e. Delivering comprehensive care in accordance with the agreed plan for services f. Recalling consumers for follow-up health care when required g. Reviewing and improving the processes of comprehensive care delivery h. Receiving a current advance care plan and incorporating it into a consumer's healthcare record
	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
	3.23 The ART service provider supports its workforce to meet the individual needs of its consumers, including: a. People with disability b. People with diverse backgrounds, sexualities, relationship statuses and parenting arrangements

Item	Action
Comprehensive care at the end of life	**Consultation note: The action below is from the National Safety and Quality Standards Primary and Community Healthcare is not considered applicable for ART service providers.** 3.24 Healthcare providers use an ART service provider's processes that are consistent with the *National Consensus Statement: Essential elements for safe and high-quality end-of-life care* to: a. Identify consumers who are at the end of life b. Use this information to plan and deliver health care

Communicating for safety

Communicating for safety aims to ensure timely, purpose-driven, effective communication and documentation that supports continuous, coordinated and safe care for consumers.

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
	3.26 The ART service provider has processes to: a. Correctly match consumers to their services b. Ensure essential information is documented in a consumer's healthcare record
Communication to support consumer referral and multidisciplinary collaboration	3.27 The ART service provider supports its healthcare providers to refer consumers to other services and collaborate with other care providers by: a. Using best practice structured communication processes b. Considering the consumer's risks, goals and preferences for health care c. Communicating information that is current, comprehensive and accurate
Maximising consumer attendance	3.28 The ART service provider has effective communication processes to maximise consumer attendance at planned appointments
Communication of critical information	3.29 The ART service provider uses its communication processes to effectively communicate critical information, alerts and risks, in a timely way, when they emerge or change: a. To relevant healthcare providers involved in the consumer's care b. In line with the consumer's preferences
	3.30 The ART service provider has communication processes for consumers to directly communicate critical information and risks about its services to their workforce

Recognising and responding to serious deterioration and minimising harm

ART service providers have systems in place to recognise and respond to serious deterioration in consumers and escalate health care appropriately.

Item	Action
Recognising serious deterioration or distress and escalating care	3.31 ART service provider's uses processes to: a. Recognise deterioration in a consumer's physical, mental or cognitive health b. Respond to a consumer within their scope of practice and call for emergency assistance c. Notify a consumer's other relevant healthcare providers when their health care is escalated
Planning for safety	3.32 The ART service provider: a. Has processes to respond to consumers who are distressed, have expressed thoughts of self-harm or suicide, or have self-harmed b. Has processes to respond to consumers who present a risk of harm to others c. Provides information on accessing other services to consumers with healthcare needs beyond the scope of the service d. Has a process that supports crisis intervention that is aligned to legislation

Section 2: Assisted Reproductive Technology Module

ART service provider governance

Item	Action
Clinical and technical governance	A01 The ART service provider establishes and maintains a clinical and technical governance framework to: a. Drive improvements in safety, quality and effectiveness b. Identify and mitigate risks related to the implementation and use of technology for its services c. Implement software updates and patches using a timely and risk-based approach d. Monitor action taken as a result of technical incidents e. Improve the competency of the workforce in reducing impacts and likelihood of cybersecurity events
Environmental sustainability	A02 The ART service provider establishes and maintains systems to adapt clinical practices to reduce its contributions to environmental impacts
Scope of services	A03 The ART service provider maintains and publishes a scope of services that it offers consumers, including the: a. procedures performed, key personnel and qualifications b. supporting services available to consumers c. donor program arrangements
Partnerships and contracts	A04 The ART service provider ensures that contracted arrangements uphold the requirements of these Standards with their engagement of: a. Workforce b. Services, including transportation of specimens c. Facilities, including where procedures are undertaken and storage of specimens d. International suppliers
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 [see Appendix A] 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

Item	Action
Andrology laboratory quality and competence	A06 The ART service provider must ensure andrology laboratories demonstrate the industry-standard requirements for quality and competence in medical laboratories **Consultation note: This action relates to compliance with ISO 15189:2012/2022, where relevant**

Supporting informed decisions

Item	Action
Information to support consent	A07 The ART service provider has processes to inform decision-making related to ART services, that includes: a. Expected outcomes b. Unexpected outcomes such as multiple pregnancies, potential complications and the short- and long-term risks c. Evidence of effectiveness relative to the consumer's age, medical history and other relevant factors d. Financial costs e. Issues that may incur future costs including management of complications f. Expected waiting times, if relevant g. How their information will be used and the circumstances in which it will be shared, if relevant h. Information on the processes for unused specimens i. Information on any regulatory requirements to be completed prior to commencement of the ART service
	A08 The ART service provider has processes to inform decision-making related to adjuvants, that includes: a. Expected outcomes and evidence related to their effectiveness, including where there is no evidence to suggest effectiveness b. Strength of evidence c. Unexpected outcomes, potential complications and the short- and long-term risks d. Financial costs
	A09 The ART service provider has processes to confirm the consent of all relevant parties: a. Following the opportunity for consumers to ask questions b. Following access and advice from appropriately qualified professionals to support informed decision-making, where requested c. Before each new ART service commences, including for each new treatment cycle d. That aligns with the *Ethical guidelines on the use of ART in clinical practice and research*

Item	Action
Advertising	A10 The ART service provider has processes to assure itself that advertising of the services it commissions or is referenced in: a. Is not false or deceptive, or likely to be misleading b. Does not offer a gift, discount or other inducement c. Does not use testimonials or purported testimonials about ART services d. Does not create unreasonable expectation of beneficial treatment e. Does not directly or indirectly encourage the indiscriminate use of ART services f. Complies with privacy guidance and legislation

Person-centred care

Item	Action
Understanding consumer needs and preferences	A11 The ART service provider's workforce and design of its systems and processes use a trauma-informed approach when: a. A consumer initiates, decides to continue or decides to discontinue use of its services b. Taking history, during care and on following-up with consumers c. Asking consumers for information, confirming decisions and understanding preferences d. Responding to feedback and complaints from consumers and people conceived through ART
Counselling services	A12 The ART service provider ensures access to counselling services for consumers that: a. Aligns with professional standards of practice and is delivered by qualified professionals with specialist knowledge of fertility issues b. Supports informed decision-making and the understanding of implications c. Provides information around the circumstances where further support may be recommended, including additional individual counselling services, joint counselling sessions or other professional support d. Uses feedback to improve the counselling service

Reproductive health

Item	Action
Reproductive education	A13 The ART service provider supports donors and recipients by providing best available evidence on: a. Preconception advice that outlines the issues surrounding weight, age, smoking, adverse environmental exposure and other relevant factors b. Alternatives to medical and surgical ART services
Pre-fertility treatment	A14 The ART service provider supports the reproductive health needs of consumers before using ART services by: a. Clinically evaluating for co-existing reproductive health or gynaecological problems b. Clinically evaluating for co-existing reproductive health or andrological problems c. Clinically evaluating for co-existing reproductive health arising from ART services d. Ensuring the appropriate pathways of referral required for endocrine, andrological and psychological expertise
Minimising multiple pregnancies	A15 The ART service provider minimises the incidence of multiple pregnancies aligned with the Guidelines on minimising incidence of multiple pregnancies [see Appendix B]

Specimen management

Item	Action
Human research	A16 The ART service provider ensures: a. All human research has been approved by a Human Research Ethics Committee and operate under the *National statement on ethical conduct in human research* b. Compliance with the *Ethical guidelines on the use of ART in clinical practice and research* c. Compliance with relevant legislation related to human research
Specimen identification	A17 The ART service provider has processes for labelling specimens that: a. Uses a minimum of three human-readable identifiers that contribute to unique identification that are linked to the donor b. Confirms labels with consumers at the time of specimen donation c. Identifies when, how and by whom the labelling has been undertaken d. Ensures barcodes are accompanied by a human-readable value

Item	Action
Matching specimens	A18 The ART service provider has processes and witnessing systems for accurately matching specimens to consumers and their procedures by: a. Verifying the labelling of specimens with donors and recipients at all stages of the procedure b. Using the minimum three human-readable identifiers c. Identifying and assessing all critical identification points where matching is prone to risk and reducing them in partnership with the workforce and consumers d. Following established escalation protocols where specimens do not conform to the specimen identification requirements
Transportation of specimens	A19 The ART service provider uses a risk-based approach for the transportation of specimens that: a. Apply to both fresh and cryopreserved specimens b. Apply to spaces not under the control of the ART service provider including hospitals, corridors, roads, footpaths and air travel c. Include criteria and a response plan for accidents and incidents during the transportation process d. Use qualified operators and confirms the intended purpose for international transport is not for commercial surrogacy
Cryostorage of specimens	A20 The ART service provider ensures the safe management and storage of cryopreserved specimens with systems and processes that: a. Use clear identification for storage containers that is resistant to degradation during cryostorage b. Ensure location of the container in the storage vessel is appropriate c. Monitor temperature variations within the storage vessel that may impact viability of stored material d. Record key information related to date of purchase, age and access e. Detect and act upon failures in safe management and storage

Supporting donor conceived people

Item	Action
Information related to donors	A21 The ART service provider: a. Ensures donor records are available to donor conceived people and their parents, aligned with legislation and jurisdictional policy requirements b. Maintains a system to ensure donor-recipient linking, including the ability to identify siblings related to a donor

Item	Action
Systems supporting donor limits	A22 The ART service provider has systems and processes to: a. Record the number of donations b. Identify legislated limitations c. Verify this information, where possible

Using data for better care

Item	Action
Contribution to clinical quality registry data	A23 The ART service provider contributes complete and accurate data to national clinical quality registries **Consultation note: This action relates to the requirement to send data to the Australian and New Zealand Assisted Reproduction Database (ANZARD)**
Using outcomes to improve practice	A24 The ART service provider: a. Uses clinical, performance and outcomes data to identify priorities for safety and quality improvement, including data from clinical quality registries b. Acts on, reviews and monitors identified priorities for safety and quality improvement c. Measures changes in safety and quality indicators and outcomes d. Provides timely information on safety and quality improvement and performance to the workforce and consumers
Risk based approach to audits	A25 The ART service provider applies a risk-based approach to the frequency and scope of audits to ensure it meets the requirements of these Standards, regulators and relevant legislation
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 [see Appendix C] b. Reviews and categorises all serious adverse events c. Acts to reduce recurrences of all serious adverse events

Advisory on not applicable actions

The Commission issues advisories to clarify the application of standards and assessment criteria. For each National Safety and Quality Standard, an advisory for the actions that may not be applicable to all service providers is published to describe where an action is considered 'Not applicable' for a given circumstance.

The draft advisory on not applicable actions for the National Safety and Quality Standards for Assisted Reproductive Technology has been adapted from Advisory PCHS26/02: Advice on not applicable actions for the National Safety and Quality Primary and Community Healthcare Standard.

Item	Action	Notes or conditions
Governance, leadership and culture	1.01	No exception
Policies and procedures	1.02	No exception
Measurement and quality improvement	1.03	No exception
Risk management	1.04	No exception
Incident management and open disclosure	1.05	No exception
	1.06	No exception
Feedback and complaints management	1.07	No exception
	1.08	No exception
Consumer populations and social determinants of health	1.09	No exception
	1.10	No exception
Healthcare records	1.11	No exception
	1.12	No exception
	1.13	Not applicable when My Health Record system is not in use.
	1.14	
Safety and quality training	1.15	No exception
	1.16	No exception
Safety and quality roles and responsibilities	1.17	No exception
Evaluating performance	1.18	No exception
Scope of clinical practice	1.19	No exception
Evidence-based care	1.20	No exception
Variation in care delivered and health outcomes	1.21	No exception
Safe environment	1.22	No exception
	1.23	No exception
	1.24	No exception
	1.25	No exception

Item	Action	Notes or conditions
Integrating clinical governance	2.01	No exception
Healthcare rights and informed consent	2.02	No exception
	2.03	Sub-action (b) not relevant to ART service providers.
Shared decisions and planning care	~~2.04~~	Action not relevant to ART service providers.
	2.05	No exception
Communication that supports effective partnerships	2.06	No exception
Accessing healthcare service information	2.07	No exception
Partnerships in the planning, design, monitoring and evaluation of services	2.08	No exception
Integrating clinical governance	3.01	No exception
Applying quality improvement systems	3.02	No exception
Partnering with consumers	3.03	No exception
Standard and transmission-based precautions	3.04	No exception
Hand hygiene	3.05	No exception
Respiratory hygiene, cough etiquette and physical distancing	3.06	No exception
Aseptic technique	3.07	Not applicable where aseptic technique is not required in the delivery of health care.
Invasive medical devices	3.08	Not applicable when invasive medical devices are not used in the delivery of health care.
Clean and safe environment	3.09	No exception
	3.10	No exception
Workforce screening and immunisation	3.11	No exception
Infections in the workforce	3.12	No exception
Reprocessing of reusable medical devices	3.13	Not applicable when sterile reusable critical medical instruments, equipment and devices are not used in the delivery of health care.
Antimicrobial stewardship	3.14	Not applicable when prescribing, supplying and/or administering antimicrobial medicines does not form part of a service's delivery of health care.

Item	Action	Notes or conditions
Documentation, provision and access to medicines-related information	3.15	Not applicable when prescribing, supplying and/or administering medicines does not form part of a service's delivery of health care.
	3.16	No exception
Safe and secure storage and supply of medicines	3.17	Not applicable when prescribing, supplying and/or administering medicines does not form part of a service's delivery of health care.
High-risk medicines	3.18	
Multidisciplinary collaboration	3.19	No exception
Health promotion and prevention	3.20	No exception
Planning and delivering comprehensive care	3.21	No exception
	3.22	No exception
	3.23	No exception
Comprehensive care at the end of life	~~3.24~~	Action not relevant to ART service providers.
Processes for effective communication	3.25	No exception
	3.26	No exception
Communication to support consumer referral and multidisciplinary collaboration	3.27	No exception
Maximising consumer attendance	3.28	No exception
Communication of critical information	3.29	No exception
	3.30	No exception
Recognising serious deterioration or distress and escalating care	3.31	No exception
Planning for safety	3.32	No exception
Clinical and technical governance	A01	No exception
Environmental sustainability	A02	No exception
Scope of services	A03	No exception
Partnerships and contracts	A04	No exception
Workforce requirements	A05	No exception
Andrology laboratory quality and competence	A06	Applicable only if andrology laboratories are freezing and storing specimens.
Information to support consent	A07	No exception
	A08	No exception
	A09	No exception
Advertising	A10	No exception

Item	Action	Notes or conditions
Understanding consumer needs and preferences	A11	No exception
Counselling services	A12	No exception
Reproductive education	A13	No exception
Pre-fertility treatment	A14	No exception
Minimising multiple pregnancies	A15	No exception
Human research	A16	No exception
Specimen identification	A17	No exception
Matching specimens	A18	No exception
Transportation of specimens	A19	No exception
Cryostorage of specimens	A20	No exception
Information related to donors	A21	No exception
Systems supporting donor limits	A22	No exception
Contribution to clinical quality registry data	A23	No exception
Using outcomes to improve practice	A24	No exception
Risk based approach to audits	A25	No exception
Reporting adverse events	A26	No exception

Glossary for the Standards

adjuvant: a therapy undertaken in addition to a recognised standard assisted reproductive technology treatment regiment, also called **add-ons**

adverse drug reaction: a response to a medicine that is noxious and unintended, and occurs at doses normally used or tested in humans for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function. An **allergy** is a type of adverse drug reaction.

adverse event: an incident that results, or could have resulted, in harm to a consumer. A near miss is a type of adverse event.

alert: warning of a potential risk to a consumer.

allergy: occurs when a person's immune system reacts to allergens in the environment that are harmless for most people. Typical allergens include some medicines, foods and latex. An allergen may be encountered through inhalation, ingestion, injection or skin contact. A medicine allergy is one type of **adverse drug reaction**.

antimicrobial resistance: failure of an antimicrobial to inhibit a microorganism at the antimicrobial concentrations usually achieved over time with standard dosing regimens.

antimicrobial stewardship: an ongoing effort by a healthcare service to reduce the risks associated with increasing antimicrobial resistance and to extend the effectiveness of antimicrobial treatments. It may incorporate several strategies, including monitoring and review of antimicrobial use.

aseptic technique: a set of practices aimed at minimising contamination and is particularly used to protect the consumer from infection during procedures.

audit: a systematic review against a predetermined set of criteria.

best possible medication history: a list of all the medicines a consumer is using at presentation. The list includes the name, dose, route and frequency of the medicine, and is documented on a specific form or in a specific place. All prescribed, over-the-counter and complementary medicines should be included. This history is obtained by a healthcare provider working within their scope of clinical practice who interviews the consumer and is confirmed, where appropriate, by using other sources of medicines information.

best practice: when the diagnosis, treatment or health care provided is based on the best available evidence, which is used to achieve the best possible outcomes for consumers.

best-practice guidelines: a set of recommended actions that are developed using the best available evidence. They provide healthcare providers with evidence-informed recommendations that support clinical practice, and guide healthcare provider and consumer decisions about appropriate health care in specific clinical practice settings and circumstances.

business decision-making: decision-making regarding service planning and management for a healthcare service. It covers the purchase of equipment, fixtures and fittings; program maintenance; workforce training for safe handling of equipment; and all issues for which business decisions are taken that might affect the safety and wellbeing of consumers, visitors and the workforce.

clinical governance: the set of relationships and responsibilities established by a healthcare service between regulators and funders, owners and managers and governing bodies (where relevant), healthcare providers, the workforce, consumers and other stakeholders to ensure optimal clinical outcomes. It ensures that:

- The community can be confident there are systems in place to deliver safe and high-quality health care
- There is a commitment to continuously improve services
- Everyone is accountable to consumers and the community for ensuring the delivery of safe, effective and high-quality health care. This includes healthcare providers, other members of the workforce and managers, owners and governing bodies (where they exist).

Depending on the size of the healthcare service, multiple roles may be carried out by the same individual.

cold chain management: the system of transporting and storing temperature-sensitive medicines and vaccines, within their defined temperature range at all times, from point of origin (manufacture) to point of administration, to ensure that the integrity of the product is maintained.

comprehensive care: health care that is based on identified goals for the episode of care. These goals are aligned with the consumer's expressed preferences and healthcare needs, consider the impact of the consumer's health issues on their life and wellbeing, and are clinically appropriate.

comprehensive care plan: a document describing agreed goals of care, and outlining planned medical, nursing and allied health activities for a consumer. Comprehensive care plans reflect shared decisions made with consumers, interventions, treatments and other activities needed to achieve the goals of care. The content of comprehensive care plans will depend on the setting and the service that is being provided, and may be called different things in different healthcare services. For example, a health care or clinical pathway for a specific intervention may be considered a comprehensive care plan.

consumer representative: a consumer who has taken up a specific role to provide advice on behalf of consumers, with the overall aim of improving health care.

critical equipment: items that confer a high risk for infection if they are contaminated with any microorganism, and must be sterile at the time of use. They include any objects that enter sterile tissue or the vascular system, because any microbial contamination could transmit disease.

critical information: information that has a considerable impact on a consumer's health, wellbeing or ongoing care (physical or psychological). The availability of critical information may require a healthcare provider to reassess or change a consumer's comprehensive care plan.

cultural safety: The former Australian Health Ministers' Advisory Council identifies that consumers are safest when healthcare providers have considered power relations, cultural differences and consumers' rights. Essential features of cultural safety are:

- An understanding of one's culture
- An acknowledgement of difference, and requirement that healthcare providers are actively mindful and respectful of difference(s)
- Informed by the theory of power relations; any attempt to depoliticise cultural safety is to miss the point
- An appreciation of the historical context of colonisation, the practices of racism at individual and institutional levels, and their impact on Aboriginal and Torres Strait Islander people's living and wellbeing, both in the present and past
- That its presence or absence is determined by the experience of the recipient of care and not defined by the healthcare provider.

The intent and the content of issues covered is consistent the Australian Health Practitioners' Regulation Agency's definition of cultural safety.

decision support tools: tools that can help healthcare providers and consumers to draw on available evidence when making clinical decisions. The tools have a number of formats. Some are explicitly designed to enable shared decision-making (for example, decision aids). Others provide some of the information needed for some components of the shared decision-making process (for example, risk calculators, evidence summaries), or provide ways of initiating and structuring conversations about health decisions (for example, communication frameworks, question prompt lists).

disability: The *Disability Discrimination Act 1992* (Cth) defines disability, in relation to a person, to mean:

- Total or partial loss of the person's bodily or mental functions; or
- Total or partial loss of a part of the body; or
- The presence in the body of organisms causing disease or illness; or
- The malfunction, malformation or disfigurement of a part of the person's body; or
- A disorder or malfunction that results in the person learning differently from a person without the disorder or malfunction; or
- A disorder, illness or disease that affects a person's thought processes, perception of reality, emotions or judgement that results in disturbed behaviour.

The World Health Organization *International classification of functioning disability and health* recognises that disability is multidimensional and is the product of an interaction between attributes of an individual and features of the person's physical, social and attitudinal environment. It broadens the perspective of disability and allows for the examination of medical, individual, social and environmental influences on functioning and disability.

diverse backgrounds: The varying social, economic and geographic circumstances of consumers who use, or may use, the services of a healthcare service, as well as their cultural backgrounds, disability status, religions, beliefs and practices, languages spoken, sexual orientation, relationship status, gender identity, gender expression and sex characteristics.

environment: the context or surroundings in which health care is delivered. Environment can also include other consumers, visitors and the workforce.

environmental impact: the factors that cause harm to the environment when not properly mitigated, including chemicals, medicines, healthcare waste and greenhouse gases (such as carbon dioxide, nitrous oxide and desflurane).

episode of care: a health problem from its first encounter with a healthcare provider through to the completion of the last encounter.

goals of care: clinical and other goals for a consumer's episode of care that are determined in the context of a shared decision-making process.

governance: the set of relationships and responsibilities established by a healthcare service between its management, workforce and stakeholders (including consumers). Effective governance provides a clear statement of individual accountabilities within the organisation to help align the roles, interests and actions of different participants in the organisation to achieve the organisation's objectives. Governance structures will be tailored to the size and complexity of an organisation.

guidelines: clinical practice guidelines are systematically developed statements to assist healthcare providers and consumer decisions about appropriate health care for specific circumstances.

hand hygiene: a general term applying to processes aiming to reduce the number of microorganisms on hands. This includes: application of a waterless antimicrobial agent (e.g. alcohol-based hand rub) to the surface of the hands; and use of soap/solution (plain or antimicrobial) and water (if hands are visibly soiled) followed by patting dry with single-use towels.

healthcare identifiers: are unique numbers assigned and used in health related information to clearly identify the consumer, the treating professional and the organisation where healthcare is provided to reduce the potential for errors with healthcare related information and communication In Australia, the Healthcare Identifiers (HI) Service is a national system for uniquely identifying, healthcare providers, healthcare organisations and individuals receiving healthcare. These include:

- Individual Healthcare Identifier (IHI) – identifies a consumer (individual) receiving healthcare. An IHI uniquely identifies individuals who receive healthcare, including Australian citizens, permanent residents and visitors to Australia
- Healthcare Provider Identifier – Individual (HPI-I) – identifies an individual healthcare provider who provides healthcare, such as general practitioners, allied health professionals, specialists, nurses, dentists and pharmacists, among others
- Healthcare Provider Identifier – Organisation (HPI-O) – identifies the healthcare provider organisation where healthcare is provided, such as hospitals, medical practices, pathology or radiology laboratories and pharmacies.

Healthcare providers (*see* definition) must be registered with the HI Service and assigned healthcare identifiers to access a consumer's My Health Record (*see* definition).

health care: the prevention, treatment and management of illness and injury, and the preservation of mental and physical wellbeing through the services offered by healthcare providers.

healthcare record: a record of a consumer's medical history, treatment notes, observations, correspondence, investigations, test results, photographs, prescription records and medication charts for an episode of care.

healthcare record system: a healthcare record and management system (that may be paper-based or electronic) that is used by healthcare providers in healthcare settings. Healthcare record information must be properly managed and safeguarded from start (record generation) to finish (record destruction) and the entire time in between.

health literacy: the Australian Commission on Safety and Quality in Health Care separates health literacy into two components – individual health literacy and the health literacy environment.

Individual health literacy is the skills, knowledge, motivation and capacity of a consumer to access, understand, appraise and apply information to make effective decisions about health and health care, and take appropriate action.

The health literacy environment is the infrastructure, policies, processes, materials, people and relationships that make up the healthcare system, which affect the ways in which consumers access, understand, appraise and apply health-related information and services.

high-risk medicines: medicines that have an increased risk of causing significant consumer harm or death if they are misused or used in error. High-risk medicines may vary between healthcare settings, depending on the types of medicines used and consumers treated. Errors with these medicines are not necessarily more common than with other medicines. Because they have a low margin of safety, the consequences of errors with high-risk medicines can be more devastating. At a minimum, the following classes of high-risk medicines should be considered:

- Medicines with a narrow therapeutic index
- Medicines that present a high risk when other system errors occur, such as administration via the wrong route
- Schedule 8 medicines.

hygienic environment: an environment in which practical prevention and control measures are used to reduce the risk of infection from contamination by microbes.

incident: an event or circumstance that resulted, or could have resulted, in unintended or unnecessary harm to a consumer; or a complaint, loss or damage. An incident may also be a near miss.

infection: an infection occurs when a microorganism enters the body, increases in number and causes a reaction in the body. This may cause tissue injury and disease.

information communications technology: Diverse set of technological tools and resources used to transmit, store, create, share or exchange information. These technological tools and resources include computers, the Internet, live broadcasting technologies, recorded broadcasting technologies and telephony.

informed consent: a process of communication between a consumer and healthcare provider about options for treatment, health care processes or potential outcomes. This communication results in the consumer's authorisation or agreement to undergo a specific intervention or participate in planned care. The communication should ensure that the consumer has an understanding of the health care they will receive, all the available options and the expected outcomes, including success rates and side effects for each option.

invasive medical devices: devices inserted through skin, mucosal barrier or internal cavity, including central lines, peripheral lines, urinary catheters, chest drains, peripherally inserted central catheters and endotracheal tubes.

jurisdictional requirements: systematically developed statements from state and territory governments about appropriate healthcare or service delivery for specific circumstances. Jurisdictional requirements encompass a number of types of documents from state and territory governments, including legislation, regulations, guidelines, policies, directives and circulars. Terms used for each document may vary by state and territory.

medicine: a chemical substance given with the intention of preventing, diagnosing, curing, controlling or alleviating disease, or otherwise improving the physical or mental wellbeing of people. These include prescription, non-prescription, investigational, clinical trial and complementary medicines, irrespective of how they are administered.

medicine-related event: any event involving treatment with a medicine that has a negative effect on a consumer's health or prevents a positive outcome. Consideration should be given to disease-specific, laboratory test-specific and consumer-specific information. Medicine-related problems include issues with medicines such as:

- Underuse
- Overuse
- Use of inappropriate medicines (including therapeutic duplication)
- Adverse drug reactions, including interactions (medicine–medicine, medicine–disease, medicine–nutrient, medicine–laboratory test)
- Noncompliance.

medicines list: a way to keep all the information about medicines a person takes together. A medicines list contains, at a minimum:

- All medicines a consumer is taking, including over-the-counter, complementary, prescription and non-prescription medicines; for each medicine, the medicine name, form, strength and directions for use must be included
- Any medicines that should not be taken by the consumer, including those causing allergies and adverse drug reactions.

Ideally, a medicines list also includes the intended use (indication) for each medicine.

multidisciplinary collaboration: a process where healthcare providers from different disciplines and/or healthcare services share clinical information to optimise the delivery of comprehensive care for a consumer.

open disclosure: an open discussion with a consumer about an incident that resulted in harm to the consumer while receiving health care. The criteria of open disclosure are an expression of regret, and a factual explanation of what happened, the potential consequences, and the steps taken to manage the event and prevent recurrence.

orientation: a formal process of informing and training a worker starting in a new position or beginning work for an organisation, which covers the policies, processes and procedures applicable to the organisation.

outcome: the status of an individual, group of people or population that is wholly or partially attributable to an action, agent or circumstance.

partnership: a situation that develops when consumers are treated with dignity and respect, when information is shared with them, and when participation and collaboration in healthcare processes are encouraged and supported to the extent that consumers choose. Partnerships can exist in different ways in a healthcare service, including at the level of individual interactions; at the level of a service, department or program; and at the level of the organisation. They can also exist with consumers and groups in the community. Generally, partnerships at all levels are necessary to ensure that the healthcare service is responsive to consumer and consumer input and needs, although the nature of the activities for these different types of partnership will depend on the context of the healthcare service.

person-centred care: an approach to the planning, delivery and evaluation of health care that is founded on mutually beneficial partnerships among healthcare providers and consumers. Person-centred care is respectful of, and responsive to, the preferences, needs and values of consumers. Key dimensions of person-centred care include respect, emotional support, physical comfort, information and communication, continuity and transition, care coordination and access to care. Also known as patient-centred care or consumer-centred care.

point of care: the time and location of an interaction between a consumer and a healthcare provider for the purpose of delivering health care.

policy: a set of principles that reflect the organisation's mission and direction.

procedure: the set of instructions to make policies and protocols operational, which are specific to an organisation.

process: a series of actions or steps taken to achieve a particular goal.

protocol: an established set of rules used to complete tasks or a set of tasks.

quality improvement: the combined efforts of the workforce and others – including consumers, consumers and their families, researchers, planners and educators – to make changes that will lead to better consumer outcomes (health), better system performance (care) and better professional development. Quality improvement activities may be undertaken in sequence, intermittently or continually.

regularly: occurring at recurring intervals. The specific interval for regular review, evaluation, audit or monitoring needs to be determined for each case. In the Primary and Community Healthcare Standards, the interval should be consistent with best practice, risk based, and determined by the subject and nature of the activity.

reports (on consumers): Documentation and information relating to a consumer's health care e.g. consumer records, referrals and scans.

respiratory hygiene and cough etiquette: A combination of measures designed to minimise the transmission of respiratory pathogens via droplet or airborne routes in healthcare settings.

reusable device: a medical device that is designated by its manufacturer as suitable for reprocessing and reuse.

risk: the chance of something happening that will have a negative impact. Risk is measured by the consequences of an event and its likelihood.

risk assessment: assessment, analysis and management of risks. It involves recognising which events may lead to harm in the future, and minimising their likelihood and consequences.

risk management: the design and implementation of a program to identify and avoid or minimise risks to consumers, employees, volunteers, visitors and the organisation.

safety culture: a product of individual and group values, attitudes, perceptions, competencies and patterns of behaviour that determine the commitment to, and the style and proficiency of an organisation's health and safety management. Positive safety cultures have strong leadership that drives and prioritises safety as well as:

- Shared perceptions of the importance of safety
- Constructive communication
- Mutual trust
- A workforce that is engaged and always aware that things can go wrong
- Acknowledgement at all levels that mistakes occur
- Ability to recognise, respond to, give feedback about, and learn from, adverse advents.

screening: a process of identifying consumers who are at risk, or already have a disease or injury. Screening requires enough knowledge to make a clinical judgement.

self-harm: includes self-poisoning, overdoses and minor injury, as well as potentially dangerous and life-threatening forms of injury. Self-harm is a behaviour and not an illness. People self-harm to cope with distress or to communicate that they are distressed.

serious deterioration: physiological, psychological or cognitive changes that may indicate a worsening of the consumer's health status.

specimens: biological material, related containers, labels and derivatives used or stored for the purposes of assisted reproductive procedures or services

standard national terminologies: a structured vocabulary used in clinical practice to accurately describe the care and treatment of consumers. Healthcare providers around the world use specialised vocabulary to describe diseases, operations, clinical procedures, findings, treatments and medicines. In Australia, terminologies include SNOMED CT-AU and Australian Medicines Terminology. Standard national terminologies are also referred to as clinical terminologies.

standard precautions: work practices that provide a first-line approach to infection prevention and control, and are used for the care and treatment of all consumers. Standard precautions include: hand hygiene, use of personal protective equipment (masks, gloves, gowns, protective eyewear) to prevent blood or bodily fluid exposure, routine environmental cleaning aligned to risk, safe use and disposal of sharps, reprocessing of reusable equipment and devices, respiratory hygiene and cough etiquette (including physical distancing), aseptic technique, linen and waste management.

supported decision making: enables a person with cognitive impairment to remain involved in decisions about their health care rather than having their decision-making capacity removed.

system: the resources, policies, processes and procedures that are organised, integrated, regulated and administered to accomplish a stated goal. A system:

- Brings together risk management, governance, and operational processes and procedures, including education, training and orientation
- Deploys an active implementation plan; feedback mechanisms include agreed protocols and guidelines, decision support tools and other resource materials
- Uses several incentives and sanctions to influence behaviour and encourage compliance with policy, protocol, regulation and procedures.

The workforce is both a resource in the system and involved in all elements of systems development, implementation, monitoring, improvement and evaluation.

timely (communication): communication of information within a reasonable time frame. This will depend on how important or time critical the information is to a consumer's ongoing health care or wellbeing, the context in which the service is provided and the clinical acuity of the consumer.

transitions of care: situations when all or part of a consumer's care is transferred between healthcare locations, providers, or levels of care within the same location, as the consumer's conditions and care needs change.

transmission-based precautions: extra work practices used in situations when standard precautions alone may not be enough to prevent transmission of infection. Transmission-based precautions are used in conjunction with standard precautions and include droplet, contact and airborne precautions or a combination of these precautions based on the route of transmission of infection.

trauma-informed: trauma-informed services and systems recognise the prevalence of trauma, particularly interpersonal trauma in our society. Trauma-informed services are aware of and acknowledge that a large percentage of individuals seeking care, treatment and support across a range of health and human service settings have lived experience of trauma that may seriously affect their mental and physical health and wellbeing.

unwarranted variation: where variation is not due to difference in consumers' clinical needs or preferences. Unwarranted variation represents an opportunity for improvement.

variation: a difference in healthcare processes or outcomes, compared to peers or to a standard such as an evidence based guideline recommendation.

workforce: all people working in a healthcare service, including healthcare providers and any other employed or contracted, locum, agency, student, volunteer or peer workers. The workforce can be members of the healthcare service or medical company representatives providing technical support who have assigned roles and responsibilities for care of, administration of, support of, or involvement with consumers in the healthcare service.

Part C: Appendices to support the Standards

Part C: Appendices to support the Standards

The appendices listed in this document support the implementation of the National Safety and Quality Standards for Assisted Reproductive Technology Services. These appendices will be published as separate documents where they can be maintained more frequently, in line with requirements from industry, regulators and best practice.

Future consultation

These appendices contain content directly from either the RTAC Code of Practice or Technical Bulletins with minor edits and formatting applied, and are included here to support the context of consultation.

The Commission will undertake a future consultation on these documents in a separate consultation.

Appendix A: Australian ART Workforce Requirements

The Organisation/ART Unit must appoint, or ensure access to the following key personnel (however titled):

- a Medical Director
- a Scientific Director
- a Nurse Manager
- a Quality Manager
- a Counselling Manager.

Medical Director

The Medical Director is responsible for the clinical management within the Organisation/ART Unit and the training, competency, and supervision of all clinicians involved in the Organisation/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 Fertility Society of Australia and New Zealand (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.

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 Organisation. 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 Organisation. The Scientific Director must:

a) Demonstrate knowledge of and continuing education in all laboratory aspects of the Organisation/ART Unit; and

b) Must also have a minimum of four full-time equivalent years of ART clinical laboratory experience in an RTAC-accredited Unit (or equivalent) and two full-time equivalent years of experience in a managerial and/or supervisory role; and

c) Have experience in the management of clinical embryology or clinical andrology laboratory as appropriate to services offered; and

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; and

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; and

f) Membership or eligibility for membership of SIRT.

Nurse Manager

The nurse manager is responsible for the nursing management within the Organisation/ART Unit and the training, competency, and supervision of all nurses involved in the Organisation/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; and

d) Membership or eligibility for membership of FNA.

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 Organisation/ART Unit.

The Counselling Manager/Senior Counsellor must:

a) Have full membership or be eligible for full membership of the Australian and New Zealand Infertility Counsellors Association (ANZICA).

b) Have a minimum of two years' experience in the management of patients with infertility

c) Demonstrate a minimum of 10-hours of engagement in ongoing professional development in the field of ART and infertility counselling over 12 months.

Quality Manager / Coordinator

a) Is responsible for the ongoing maintenance of the quality management system with input from all personnel; and

b) Has qualifications or knowledge and experience in quality management systems; and

c) Recognises the importance of quality management systems and is allocated dedicated time for the role of quality manager or coordinator.

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 ART Unit must provide evidence that all Certified Affiliate Units, staff and other persons are authorised to perform the functions that they have been employed or engaged to carry out for or on behalf of the ART Unit

b) The management and care of the patient within an ART Unit must be provided or directly supervised by a registered medical specialist who is a Fellow of the RANZCOG, or

c) 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

d) 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

e) 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

f) arrangement must be disclosed formally to the patient/s. Contingency arrangements in the event of an emergency must be in place.

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 Organisation/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) Membership or eligibility 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.

Laboratory Manager/Supervisor

The Laboratory Supervisor is responsible for the day-to-day clinical management within the ART Unit and supports the Scientific Director in the training, competency, and supervision of all clinical embryologist involved in the Organisation/ART Unit. 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) 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; and

b) Must 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 policies and procedures, together with evidence of ongoing communication, exist to ensure clear and effective support from the Scientific Director; and

c) 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; and

d) Membership or eligibility for membership of SIRT.

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; and

d) Membership or eligibility for membership of FNA.

If no permanent Nurse Unit Manager/Senior Nurse is available, the Nurse Manager must be in regular and ongoing contact, with 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.

Counsellor

The Counsellor must have:

a) Full membership or be eligible for full membership of the Australian and New Zealand Infertility Counsellors Association (ANZICA) or be a provisional member of ANZICA. If the counsellor is a provisional member of ANZICA they are required to

    i) demonstrate that they have had at least 200 client contact hours over a minimum 6-month period in the area of fertility counselling (as verified by an ANZICA Supervisor); and

    ii) have had a minimum of 10 hours of supervision with a full ANZICA member; and

    iii) it is recommended that they attend professional development such as the START course offered by the FSANZ and other activities such as ANZICA webinars, training days and state meetings.

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.

Appendix B: Guidelines on minimising incidence of multiple pregnancies

ART services 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.

Appendix C: Requirements for adverse event reporting for ART services

The events that ART services are required to report are defined in the table below.

Serious adverse events are those 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: – 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 (see exclusion note below)* – severe mental health event – death *Note, specific medical or surgical conditions that define a serious adverse event exclude the following: • ectopic pregnancy • complications arising from a miscarriage • pain, bloating, nausea or other symptoms where the reportable serious events defined above for OHSS, infection, torsion etc have been excluded and hospital admission is < 48 hours.

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