Quality & Accreditation Institute

Centre for Accreditation of Health & Social Care

Accreditation Standards for Assisted Reproductive Technology (ART) Centres

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(Final Draft for Public Consultation)

For Public Consultation

The QAI's Centre for Accreditation of Health and Social Care (CAHSC) has revised **accreditation standards for Assisted Reproductive Technology (ART) Centres.**

We would greatly appreciate if you could please take the time to review the attached draft Standard and provide us with your feedback. These standards are posted on our website www.qai.org.in.

Thank you in advance for your co-operation and we look forward to receiving your feedback.

We would appreciate if you could send your feedback to rehma@qai.org.in by 03 August 2024.

Introduction

Infertility, the word itself alerts the mind of everyone, though it is not life threatening but has a much larger impact than by a deadly disease. Who can understand best the mental agony, trauma and social stigma attached than infertile couples themselves? Rapidly changing environmental conditions and socio-economic factors are resulting into new problems as far as human health and well-being is concerned. One such problem is increasing cases of infertility which leads to difficult situations related to maternal and reproductive problems, social status of both men and women in general but for women in particular. Infertility is becoming a huge concern both in rural and urban areas.

Global infertility prevalence rates are difficult to determine, due to the presence of both male and female factors which complicate any estimate which may only address the woman and an outcome of a pregnancy diagnosis or live birth. One in every four couples in developing countries had been found to be affected by infertility, when an evaluation of responses from women in Demographic and Health Surveys from 1990 was completed in collaboration with WHO in 2004. The burden remains high. A WHO study, published at the end of 2012, has shown that the overall burden of infertility in women from 190 countries has remained similar in estimated levels and trends from 1990 to 2010. WHO- Human Reproduction Programme (HRP), (the UNDP/UNFPA/UNICEF/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction) is the main instrument within the United Nations system for research in human reproduction, bringing together policy-makers, scientists, health care providers, clinicians, consumers and community representatives to identify and address priorities for research to improve sexual and reproductive health. Infertility is one of the most important component of this programme.

In view of this serious problem, the role of Assisted Reproductive Technology (ART) is very important. For the purpose of these accreditation standards, ART would mean all techniques that attempt to result into a pregnancy by manipulating the sperm or oocyte outside the body, and transferring the gamete or embryo into the uterus. ART would include In Vitro Fertilisation (IVF), Gamete Intra Fallopian Transfer (GIFT), Intra Cytoplasmic Sperm Injection (ICSI) etc. amongst the most common procedures.

We all know that Robert Geoffrey Edwards (27 September 1925 – 10 April 2013) was awarded the Nobel Prize in 2010 for the “development of human in vitro fertilisation (IVF) therapy.” His work began in the 1950s, culminating in the first child born in 1978 as a result of IVF with clinical management by Gynaecologist, Patrick Christopher Steptoe (9 June 1913 – 21 March 1988). Globally, approximately five million children have been born as a result of IVF, an innovation defined as “a milestone in modern medicine.”

It is therefore essential that the facilities engaged in carrying out ARTs support the innovative initiatives of national and international centres and governments by providing reliable and safe treatments to its patients. One mechanism to ensure that such facilities implement a robust system to provide reliable and safe treatments is Accreditation.

Accreditation of healthcare facilities is not a new concept now. It is a widely accepted tool for recognition of healthcare facilities through a process of self and external evaluation. Accreditation is always awarded against a set of standards, and therefore it is essential to develop standards for accreditation either for a

healthcare facility or for a specific care or service. ART treatments are quite challenging, complex and risk associated. It is therefore thought by experts in this area to develop accreditation standards to start an accreditation programme for healthcare facilities offering ARTs to standardise the three pillars i.e structures, process and outcomes. It was felt that 'Patient Safety' being the core component of these standards might support healthcare facilities to have better outcomes and safe care.

In line with the international principles for developing standards, development process began with constituting a Technical Committee comprising of experts in this field representing a wider range of such services. A literature review of such specific accreditation standards available elsewhere including guidelines from Indian Council of Medical Research was done and a framework was prepared. These standards were developed using the principles of International Society for Quality in Health Care (ISQua) for developing the standards which also follow framework of RUMBA (Relevant, Understandable, Measurable, Beneficial and Achievable). Standards were subjected to a wide consultation process by inviting comments from stakeholders by hosting on our website and also disseminating the information through emails to various ART Centres. Standards were pilot tested before finalising.

These standards are comprised of 10 chapters, 101 standards and 545 criteria. Criterion is the measurable component of the standard. We are hopeful that ART centres as well as their patients would find these useful and we seek your feedback on continuous basis to improve them as part of our regular review and revision process which will generally takes place every three to four years.

A guidance document to provide interpretation to these standards shall be published in time to come.

On behalf of the Board of QAI's Centre for Accreditation of Health & Social Care (CAHSC), I would like to immensely thank the Technical Committee, reviewers, piloting centres and other stakeholders involved for their efforts, time and commitment leading to the development of these accreditation standards for the first time in country.

Dr. B.K. Rana
Founding CEO, QAI

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Chapter 1
Governance and Leadership (GAL)

Introduction

Each centre requires a governance structure that is ultimately responsible for the quality and safety of services provided. This responsibility is derived from its legal identity and operational authority for all activities undertaken by the centre within the ambit of applicable laws and regulations. Each centre, regardless of its complexity, also has a formal structure. Leaders ensure that a system exists that promotes safety and quality, provision of services that meet the needs of patient, availability of adequate resources e.g. human, financial & physical and, monitoring and evaluation of improvement activities.

STANDARDS AND CRITERIA		
Standard	**GAL.1:**	**The Governing body is identified and is collectively responsible and actively engaged in quality & safety.**
Criterion	**a.**	The operational responsibilities and accountabilities of the governing body are described in a written document(s).
	b.	The governing body document its vision, mission and values.
	c.	The governing body approves the centre's programme for quality and patient safety and regularly receives and acts on reports of the quality and patient safety programme.
	d.	The governing body is responsible for complying with applicable laws and regulations.
Standard	**GAL.2:**	**The structure and authority of the governing body are described in bylaws, policies and procedures, or similar documents.**
Criterion	**a.**	The governing body approves the centre's strategic plans, operational plans, policies, and procedures, and approves, periodically reviews, and makes public the centre's mission statement.
	b.	The governing body approves the centre's capital and operating budget(s) and allocates other resources required to meet the centre's mission.
	c.	The governing body approves the centre's participation in health care professional education and research and monitors quality of such programmes.
Standard	**GAL.3:**	**Centre leadership is identified and is collectively responsible for creating the programmes and policies needed to fulfil the centre 's mission.**
Criterion	**a.**	The centre's leadership are identified by title and name, and their collective accountabilities are described in written documents.
	b.	Responsibility for the clinical oversight of services is assigned and supported by the centre.
	c.	Centre leadership is responsible for creating the policies and procedures necessary to carry out the mission and needs of the patients served by the centre
	d.	Centre leadership communicates the centre's vision, mission, goals, policies, and plans to staff and other stakeholders

	e.	The centre leadership ensures that there is a professional staff structure(s) used by medical, nursing, and other department/service leaders to carry out their responsibilities and authority
Standard	**GAL.4:**	**Centre leadership plans, develops, and implements a quality improvement and patient safety programme.**
	a.	Centre leadership participates in developing and implementing quality improvement and patient safety programme.
	b.	Centre leadership reports on the quality and patient safety programme at least quarterly to the governing body.
	c.	Centre leadership reports to the governing body include, at least quarterly, the number and type of sentinel events along with the root cause analysis and action taken reports.
	d.	Centre leadership ensures that contracts and other arrangements are included as part of the centre's quality improvement and patient safety programme
Standard	**GAL.5:**	**The governing body receives reports on the quality and safety of care delivered.**
Criterion	**a.**	Report on all processes or system failures
	b.	Report on number and type of critical incidents
	c.	Report on quality and safety related performance indicators.
	d.	Report on results from peer review activities like different assessment/audits.
Standard	**GAL.6:**	**The assigned leaders communicate effectively with each other on issues of quality and safety.**
Criterion	**a.**	The Governing Body, centre Leadership and Department/service leaders collaborate regularly to meet their obligations effectively
	b.	Department/service leaders participate and implement quality and patient safety measures in monitoring and improving patient care specific to their department/service
	c.	Measures selected by the department/service leaders that are applicable to evaluating the performance of physicians, nurses, and other professional staff participating in the clinical care processes are used in the staff's performance evaluation
	d.	Department/service leaders select and implement clinical practice guidelines, and related clinical pathways and/or clinical protocols, to guide clinical care
	e.	Leaders discuss issues that affect the services being offered may include but not limited to problems arise, proposed solutions, feedback from service users and quality improvement activities.
Standard	**GAL.7:**	**The centre plans services to meet the current and future needs of the patient population it serves**
Criterion	**a.**	The centre provides services that are in alignment with the mission, vision and strategic plan of the centre.
	b.	The centre determines the scope of services using a planning process.
	c.	The centre has a defined scope of service.
	d.	The centre develops an annual operating budget.

Standard	**GAL.8:**	**The centre delivers services and makes decisions in accordance with its values and ethical principles.**
Criterion	**a.**	centre leadership establishes a framework for the centre's ethical management that promotes a culture of ethical practices and decision making to ensure patient safety and protection of their rights.
	b.	The centre's framework for ethical management has a mechanism to raise and resolve ethical concerns by staff and/or patients.
	c.	The values of the centre are defined and communicated to staff
	d.	The centre discloses its ownership and any conflicts of interest.
	e.	The centre honestly portrays its services to patients.
	f.	The centre accurately bills for services.

Chapter 2
Human Resource Management (HRM)

Introduction

Human Resource include all the people that work in, for or with the centre and they are integral to ensuring the delivery of quality, patient-centred and safe care. The centre must be able to assure the public or patients that it can meet their needs and deliver quality and safe care through a team of dedicated and qualified staff. The support includes the management team providing a safe physical environment for staff to work in, which is free from harassment or accidents.

STANDARDS AND CRITERIA		
Standard	**HRM.1:**	**The centre has a documented process for human resource planning.**
Criterion	**a.**	The centre uses its mission, volume, and mix of patients, services, and medical equipment in planning.
	b.	Applicable laws and regulations are incorporated into the planning.
	c.	The centre has adequate manpower to provide the defined scope of services.
	d.	The centre has suitably qualified, skilled and trained manpower to achieve its service objective in accordance regulatory requirement applicable for ART centre
	e.	The centre has a documented job description for all its staff and is kept current according to the centre's policy.
	f.	The centre applies due diligence to ensure that potential staff is free from any criminal background.
Standard	**HRM.2:**	**The centre has a documented recruitment process.**
Criterion	**a.**	The centre uses documented recruitment process.
	b.	The recruitment process of the centre ensures the recruitment of people with required competencies, skills or knowledge to deliver safe and quality care
	c.	There is a process for evaluation/re-evaluation after recruitment/probation of new employees
	d.	There is a documented procedure for orientation of staff at the time of induction. The induction must be completed within 15 days of joining.
	e.	Induction includes providing information about centre, job roles and responsibilities, its policies, employee and patient's rights and responsibilities. Effectiveness of induction training is assessed.
Standard	**HRM.3:**	**The centre has a documented system of maintaining personnel files for all staff members.**
Criterion	**a.**	Personnel file is documented that contains at least credentials, verification of credentials, privileging, offer/appointment letter, job description, pre-employment and annual health checkup, vaccination records, induction training records, performance appraisal, updated training records, complaint, grievance and disciplinary action taken records, if any.

	b.	A personnel file is maintained and updated as necessary for each staff member including visiting consultant
Standard	**HRM.4:**	**The centre has a documented performance evaluation process.**
Criterion	**a.**	The centre has a standardised documented process for evaluating the performance of its staff.
	b.	Performance evaluation is done on the pre-determined criteria and is documented. Parameters are customized as per the category of care providers.
	c.	The process describes the frequency of evaluation at least once in a year.
Standard	**HRM.5:**	**The centre has a continuous professional development programme.**
Criterion	**a.**	There is a documented professional development and training policy for staff.
	b.	Staff is provided required training as and when required and record is maintained.
	c.	Training also occurs when job responsibilities change/new equipment is introduced.
	d.	Staff are trained on the organisation's safety programme.
	e.	Staff are trained in occupational safety aspects.
	f.	Staff are trained in handling fire and non-fire emergencies.
	g.	Staff are trained on the organisation's quality improvement programme
	h.	Staff is trained on respecting patient's preferences and choices, informing about their options for care and treatment, and obtaining informed consent.
	i.	Evaluation of training programme and its effectiveness is done by the organisation.
Standard	**HRM.6:**	**A documented disciplinary, complaint and grievance handling system exists in the centre.**
Criterion	**a.**	Disciplinary, complaint and grievance handling policies and procedures are documented
	b.	These policies and procedures also address requirements of applicable laws.
	c.	Such policies and procedures are made available to each staff.
	d.	Actions are taken to redress the complaints and grievance and same is documented.
Standard	**HRM.7:**	**A documented policy exists to address health needs of staff**
Criterion	**a.**	The policy addresses at least pre-employment health check-ups, annual health check-ups, pre and post exposure prophylaxis, occupational health hazards.
	b.	The staff is subjected to a pre-employment medical examination, annual health check-ups and results are recorded in the personnel file.
	c.	Staff is vaccinated and record is maintained.
Standard	**HRM.8:**	**The centre has a documented system of credentialing and privileging of medical and nursing staff.**
Criterion	**a.**	The centre identifies the medical professionals those are permitted by law to provide respective care.
	b.	The centre identifies the nursing professionals those are permitted by law to provide respective care.
	c.	The centre identifies embryologist and andrologist those are permitted by law to provide respective care.

	d.	Such professionals are privileged to provide required care as per their credentials based on education, training and experience.
Standard	**HRM.9:**	**There is a process for credentialing and privileging of para-medical professionals, permitted to provide patient care without supervision.**
Criterion	**a.**	Para-medical professionals for example technicians, OT technician, counsellors, pharmacists etc. permitted by law, regulation and the organisation to provide patient care without supervision are identified.
	b.	Para-medical professionals are granted privileges in consonance with their qualification, training, and experience.

Chapter 3
Facility and Risk Management (FRM)

Introduction

The centre will prevent people from receiving unsafe care and treatment and prevent avoidable harm or risk of harm. Safe, high-quality care and support is intrinsically linked to how resources are used including how they are planned, managed and delivered. Centres must assess the risks to people's health and safety during any care or treatment and make sure staff have the skills, experience and competence to keep patients safe. Premises and equipment must be safe and available in sufficient quantities. Good clinical and good laboratory practices are followed in all its operations. Centre must prevent the spread of infection.

STANDARDS AND CRITERIA		
Standard	**FRM.1:**	**Facility Management is guided by applicable laws and regulations**
Criterion	**a.**	The Management of the centre is familiar with and abide by the local and national laws that govern the facility.
	b.	Planning, designing, development and maintenance of the infrastructure is in accordance with applicable laws & regulations to ensure optimum quality and safety outcomes.
	c.	The updated drawings are available which deals with site-layout, floor plans and emergency escape routes.
	d.	The management ensures the availability of adequate infrastructure to provide the defined scope of services.
	e.	The centre ensures required audits and inspections by appropriate authorities along with action taken reports.
	f.	When the centre is located inside a multiuse building, management obtains evidence of compliance with relevant laws, regulations, codes, facility inspection reports, utility maintenance requirements, and other requirements related to shared systems and building issues.
Standard	**FRM.2:**	**There is a designated individual to oversee the facility management and safety structure.**
Criterion	**a.**	Oversight and direction of the facility management and safety structure is assigned to an individual qualified by experience and training
	b.	Roles and responsibilities of such individual are defined and documented
	c.	The qualified individual ensures that the facility management and safety programmes are current, fully implemented and monitored.
	d.	The qualified individual is responsible for coordinating and managing risk assessment and reduction activities for the facility management and safety structure.
Standard	**FRM.3:**	**There is a documented safety and security plan to provide safe and secured environment to patient, visitors & staff.**
Criterion	**a.**	The centre has a safety and security plan which is dependent on identified safety and security threats
	b.	The plan provides and maintains safe and secure environment for patients,

		staff and visitors.
	c.	The centre prioritizes the risks, identifies goals and improvements, and implements improvements to reduce and eliminate risks.
	d.	The centre conducts inspection of the facility at least once in a year and as and when needed to identify security and safety threats and findings from inspection are acted upon.
	e.	There is signage both internally and externally available in the centre in a language understood by patient, family and community to reduce risks as applicable.
Standard	**FRM.4:**	**There is a documented plan and system for management of hazardous material and waste.**
Criterion	**a.**	The centre has a list of identified hazardous materials and waste in the centre
	b.	The handling and disposal of hazardous materials and waste are in accordance with the laws and regulations
	c.	The centre maintain documentation including any permits, licenses, or other regulatory requirements
	d.	The centre has a documented plan that identifies the type, quantities, and locations of hazardous materials and has a complete inventory, which is updated at least annually
	e.	Documented plan includes methods of handling, storage and use of hazardous materials and waste
	f.	Plan includes availability of material safety data sheet for all relevant hazardous materials at the user end in a language understandable to the user.
	g.	There is a procedure of reporting and investigating hazardous materials spills, exposure etc.
	h.	Staff is educated on plan & trained on the proper use of personal protective equipment, needle stick injuries and procedures during use, spill or exposure to hazardous materials.
	i.	All hazardous materials and waste are properly labelled.
Standard	**FRM.5:**	**The centre has round the clock provision of potable water and electricity.**
Criterion	**a.**	The centre ensures availability of potable water and electricity round the clock.
	b.	The centre has alternative sources of water and electricity.
	c.	There is a potable water and electricity management programme that includes inspection, maintenance and testing of the systems on regular basis.
	d.	The centre assesses for and reduces the risks of interruption, contamination, and failure of water & electricity
	e.	The quality of water should be checked quarterly.
	f.	The centre tests the availability and quality of the alternative source(s) of

		water.
Standard	**FRM.6:**	**There is a documented emergency response plan.**
Criterion	**a.**	The centre develops and implements a written programme for safety to protect all occupants of the centre's facilities from fire, smoke, and non-fire emergencies
	b.	The fire safety programme includes equipment/systems for the early detection and alarm notification of fire and smoke
	c.	The fire safety programme includes the safe exit from the facility through free and unobstructed access to exits with clearly visible exit signages
	d.	Inspection, testing, and maintenance of all fire safety equipment and systems are documented, including results and corrective actions
	e.	The fire safety plan is tested annually for effectiveness and staff participate in it.
	f.	The centre identifies the trained individual to oversee functions of the plan.
	g.	Staff are educated on the fire safety plan
Standard	**FRM.7:**	**There is a documented equipment management programme including biomedical equipments.**
Criterion	**a.**	The centre ensure availability of required equipments including biomedical equipments as per its scope & service
	b.	There is defined process of equipment procurement
	c.	The centre maintains a list of all equipment required and usage logs are maintained.
	d.	There is a documented operational and maintenance (preventive/ breakdown) plan for all equipment.
	e.	Qualified staff operates, inspect and maintain equipment.
	f.	Equipments are periodically inspected and calibrated as applicable to ensure proper functioning.
	g.	There is a maintenance plan for heating, ventilation and air-conditioning.
	h.	The centre has a process for monitoring and acting on reportable incidents, problems, and failures of equipments.
	i.	There is a documented equipment replacement and disposal, as applicable.
Standard	**FRM.8:**	**The centre has a programme for usage of medical gases, vacuum and compressed air.**
Criterion	**a.**	Documented procedures govern procurement, handling, storage, distribution, usage and replenishment of medical gases.
	b.	Medical gases are handled, stored, distributed and used in a safe manner.
	c.	Alternate sources for medical gases, vacuum and compressed air are provided for, in case of failure.
	d.	The centre regularly tests these alternate sources.
	e.	There is a documented operational, inspection, testing and maintenance plan for, piped medical gas, compressed air and vacuum installation.
Standard	**FRM.9:**	**There is appropriate space available for reception and handling of specimens/gametes/embryos**

Criterion	**a.**	The collection, screening, storage and handling of gametes is done by entity as permitted by law
	b.	There should be a designated area for reception of specimens.
	c.	There should be defined areas for handling and processing of specimens/ gametes (sperms/ oocytes)/ embryos.
	d.	The highest possible standards should be followed in the storage and handling of gametes and embryos in respect of their security, and with regard to their recording and identification.
Standard	**FRM.10:**	**Good practices are followed in Andrology and Embryology laboratory.**
Criterion	**a.**	There shall be a separate room with a laminar air flow for semen processing, preferably close to the semen collection room.
	b.	The embryology laboratory must have facilities for control of temperature and humidity and must have filtered air with an appropriate number of air exchanges per hour
	c.	Good Laboratory Practice (GLP) guidelines must be followed
	d.	Provision for the safe disposal of biological waste and other materials (syringes, glass slides, etc.) should be in place.
	e.	Each batch for inhouse preparation of culture medium should be tested for sterility, endotoxins, osmolality and pH
	f.	For inhouse media preparation supplemented with serum; should be tested for antibodies to HIV 1 and 2, Hepatitis B Surface Antigen and Hepatitis C RNA
	g.	Laboratory access is restricted to authorised personnel.
	h.	Administrative space, changing room, hand washing facility and cleaning/sterilization room should be separate from laboratory.
	i.	Procedures involving gamete or embryo manipulation should be performed in a controlled environment.
	j.	Aseptic technique should be used at all times for handling of gamete and embryo.
	k.	Appropriate measures should be taken to ensure that oocytes and embryos are maintained at 37 degrees centigrade during handling/observation.
	l.	Identifying information marked on the culture dish/tube should be cross referenced to the patient and the patient's documentation.
	m.	Procedures should be in place to ensure correct patient identification at all stages.
	n.	Labelling of dishes/tubes containing oocytes, embryos, or sperm should be permanent.
	o.	Temperature and pH of media must be maintained during the procedure.
	p.	The status of each oocyte should be recorded.
	q.	The laboratory's Quality Management System should be systematically reviewed annually to ensure continuous improvement of the entire process by identifying current challenges, problems, errors or improvements
	r.	An audit system, both internal and external, must be in place to verify compliance of all procedures with SOPs and requirements. Any findings, corrective actions and their effectiveness must be documented

Standard	**FRM.11:**	**Proper procedure for Oocyte identification, sperm preparation, insemination of oocytes is followed.**
Criterion	**a.**	Double witnessing/RI witnessing should be followed all time to ensure correct identification.
	b.	All procedures for Oocyte identification should be carried out using sterile technique and appropriate temperature is maintained.
	c.	Records of sperm preparation are maintained with proper labelling with the patient identifying information
	d.	Records should be kept of sperm parameters (concentration, motility, morphology) and other characteristics such as semen volume, time of liquefaction, contamination with other cells etc.
	e.	The method of sperm preparation should be recorded, including details of any variation on the standard laboratory protocol
	f.	A record should be kept of post preparation sperm parameters and of any dilution carried out prior to insemination
	g.	During the insemination procedure temperature, humidity and pH of culture media should be controlled appropriately.
	h.	A record should be kept of the time of insemination and the sperm concentration used
	i.	All oocytes that have been inseminated should be examined for the presence of pronuclei at 16 to 20 hours post insemination
Standard	**FRM.12:**	**There is a documented process for embryo culture and grading.**
Criterion	**a.**	The stage of embryo development/grading should be documented all the time till the time of transfer
	b.	The patient records for embryo transfer should include details of: • Batch number and type of media used for transfer • Time from oocyte retrieval to transfer • Time from oocyte insemination to transfer • The number and developmental stage of embryos at transfer • Fate of excess embryos Type of catheter used for transfer
	c.	Sterile disposable catheters should be used for transfer.
Standard	**FRM.13:**	**Cryopreservation of embryos follows good practices.**
Criterion	**a.**	Separate room for cryopreservation is available
	b.	Cryopreservation process is followed in compliance with the ART act
	c.	Adequate ventilation and low oxygen alarms should be installed
	d.	Cryo-storage units should be continuously monitored and equipped with alarm systems, detecting any out-of-range temperature and/or levels of liquid nitrogen (LN2)
	e.	Protection devices (e.g. glasses, face shield, cryo-gloves, apron, footwear) should be used during LN2 handling.
	f.	In order to minimise any risk of transmission of infection via liquid nitrogen, embryos should be stored in receptacles (i.e. straws, vials etc).
	g.	For patients having embryos frozen, consideration should be given to screening for Hepatitis B and C, and HIV

	h.	Documentation on stored embryos should include:
	i.	• The type and batch number of cryoprotectant used. • The stage of embryo development. • The number of embryos in each straw/vial. • The number of straws/vials stored per patient
	j.	Straws/vials containing gametes must be clearly and permanently labelled with reference to patient details and their unique identification code.
	k.	Storage records should be kept in both the patient's individual records and the storage records for individual nitrogen banks.
Standard	**FRM.14:**	**An annual audit of stored gametes and embryos must be carried out, cross referencing contents with storage records**
Criterion	**a.**	Storage records should include precise details of the location of the vials/straws
	b.	Documentation of thawing procedures should include morphological changes seen during thawing and the time period of culture prior to transfer
	c.	Temperature and pH of the gametes must be maintained during manipulation
	d.	Micro tools must be sterile and should never be used for more than one patient
Standard	**FRM.15:**	**Micromanipulation activities follow good practices.**
Criterion	**a.**	Personnel performing micromanipulation techniques should be properly qualified.
	b.	All equipment required must be properly maintained
	c.	Temperature and pH of the gametes must be maintained during manipulation
	d.	Micro tools must be sterile and should never be used for more than one patient
Standard	**FRM.16:**	**There is adequate facility for carrying out surgical and invasive procedures**
Criterion	**a.**	There is a dedicated operation theatre to carry out ART surgical and invasive procedures.
	b.	Operating room shall be adjacent to Embryology laboratory and embryo transfer room
	c.	Entry to the sterile area must be strictly controlled by an anteroom for changing footwear, an area for changing into sterile garments and a scrub-station.
	d.	There is a monitoring mechanism of operation theatre to ensure sterility.
	e.	The operation theatre must be equipped for emergency resuscitative procedures.
Standard	**FRM.17:**	**There is adequate facility for carrying out sterilization activities**
Criterion	**a.**	A separate facility must be available for sterilizing all surgical items
	b.	Sterilization room shall be in close proximity to Operation theatre and laboratories
	c.	Appropriate zoning and environmental control is ensured in the Sterilization room

	d.	The centre follows professional practice guidelines and manufacturer guidelines for disinfection& sterilization techniques that best fit the type of situations for sterilization and devices and supplies being sterilized
	e.	Methods for medical/surgical cleaning, disinfection, and sterilization are documented, coordinated and uniformly applied throughout the facility.
	f.	Clean and sterile supplies are properly stored in designated storage areas that are clean and dry and protected from dust, moisture, and temperature extremes
	g.	Staff processing medical/surgical equipment, devices, and supplies are oriented to, trained in, and demonstrate competency in cleaning, disinfection, and sterilization.
Standard	**FRM.18:**	**A documented risk management plan is implemented.**
Criterion	**a.**	There is a documented risk management plan.
	b.	There is a process for proactive identification, evaluation and management of immediate and potential risks to patients and staff.
	c.	The centre takes appropriate actions to eliminate or minimise these risks.
	d.	Patient safety incidents are identified, managed and responded to.
	e.	The centre encourages to report patient safety incidents to the management in a timely manner.
	f.	The centre has an induction and ongoing training for the staff on the identification, management and reporting of patient-safety incidents.
	g.	The centre prevents patients and staff from abuse.
	h.	The centre has system in place to implement recommendations from investigations of adverse event and to monitor the effectiveness of actions taken.

Chapter 4
Information Management System (IMS)

Introduction

An effective information management system is based on the information needs of the centre. The system should be able to capture, transmit, store, analyse, utilise and retrieve information as and when required for improving clinical outcomes as well as individual and overall performance of the centre. Information can be in any form- paper or electronic or a mix of both.

STANDARDS AND CRITERIA		
Standard	**IMS.1:**	**Documented policy and procedure exists to meet the information needs of the centre.**
Criterion	**a.**	The information needs of the patients, visitors, staff, management external agencies and community is identified and documented.
	b.	Information management is in accordance with the identified need with documented policies and procedures.
	c.	The information needs of the centre are appropriate to the scope of the services being provided by the centre.
	d.	The centre contributes to external databases in accordance with the law and regulations.
	e.	A maintenance plan for information technology and communication network is implemented
Standard	**IMS.2:**	**The centre implements a document control system.**
Criterion	**a.**	The centre has a documented policy and procedure for document control.
	b.	System covers documents both generated internally and from external sources.
	c.	Documented procedures exist for storing and retrieving documents.
Standard	**IMS.3:**	**The centre implements a system of controlling and managing of data.**
Criterion	**a.**	Formats for data collection are standardised.
	b.	Necessary resources are available for collection and analysis of data.
	c.	Documented procedures are laid down and implemented for timely and accurate dissemination of data.
	d.	Documented procedures exist and implemented for storing and retrieving data.
	e.	Appropriate clinical and managerial staff participates in selecting, integrating and using data.
	f.	The controlling, managing and storing of data is in accordance with the applicable laws.
Standard	**IMS.4:**	**The centre defines what constitutes a medical record and maintain it.**
Criterion	**a.**	The centre has a documented policy and procedure for medical records maintenance, storing and retrieving.
	b.	The medical record contains information regarding assessment findings, reasons for admission, diagnosis, care plan and consent.

	c.	The medical record contains the results of tests carried out and the care provided.
	d.	Operative and other procedures performed are incorporated in the medical record.
	e.	When patient is transferred to another centre, the medical record contains the date of transfer, the reason for the transfer and the name of the receiving centre
	f.	The medical record contains a copy of the discharge summary duly signed by appropriate and qualified personnel.
Standard	**IMS.5:**	**The centre maintains complete and accurate medical record for every patient.**
Criterion	**a.**	Every medical record has a unique identifier.
	b.	Centre policy identifies those authorised to make entries in medical record.
	c.	Entry in the medical record is named, signed, dated and timed
	d.	The author of the entry can be identified.
	e.	The contents of medical record are identified and documented.
	f.	The centre has a documented policy for usage of abbreviations and develops a list based on accepted practices.
	g.	The record provides a complete, up-to-date and chronological account of patient care.
	h.	Provision is made for round the clock availability of the patient's record to care providers to ensure continuity of care.
Standard	**IMS.6:**	**The centre has documented policy and procedure in place for maintaining confidentiality, integrity and security of records, data and information.**
Criterion	**a.**	Documented policy and procedure exist for maintaining confidentiality, security and integrity of records, data and information.
	b.	The policy and procedure is in accordance with the applicable laws
	c.	The centre ensures safeguarding of data & record against loss, destruction and tampering.
	d.	The centre uses appropriate technology for improving confidentiality, integrity and security.
	e.	Privileged health information is used for the purposes identified or as required by law and not disclosed without the patient's authorisation.
	f.	A documented procedure exists to address issue related to patients/physicians and other public agencies requesting access to information in the medical record in accordance with the local and national law
Standard	**IMS.7:**	**There is documented policy and procedure exists regarding retention time of records, data and information.**
Criterion	**a.**	Documented policy and procedure are in place on retaining the patient's clinical records, data and information in accordance with the local and national laws and regulations.
	b.	Confidentiality and security of such records and information is ensured.
	c.	The updation and destruction of medical records, data and information is in accordance with the laid-down policy and applicable law.
Standard	**IMS.8:**	**The centre regularly conducts medical record audit.**

Criterion	**a.**	The medical record audit is periodically conducted as per the documented policy.
	b.	The audit is conducted by team of trained individuals including clinical staff.
	c.	The audit covers timeliness, legibility and completeness of the medical records.
	d.	The audit includes records of both active and discharged patients.
	e.	Appropriate corrective and preventive measures, against any deficiency observed, are undertaken within a defined period of time are documented and reviewed.

Chapter 5
Continual Quality Improvement (CQI)

Introduction

Quality Improvement recognises that the safety of the patient is paramount. A centre that is focused on quality improvement continually looks for ways to promote patient safety and quality of care. Quality and safety improvements in healthcare include a patient-safety improvement programme that requires healthcare providers to proactively identify risk and to plan, implement and evaluate necessary changes to improve the quality and safety of services.

The centre ensures regular evaluation of these programmes through performance indicators and benchmarks to identify both positive outcomes and areas for improvement. Any necessary actions to improve the quality and safety of the services are implemented and learning is disseminated both internally and externally.

STANDARDS AND CRITERIA		
Standard	**CQI.1:**	**The Management plans and leads the quality improvement programme in the centre.**
Criterion	**a.**	Leaders of the centre are accountable for service performance.
	b.	Leaders lead and plan the quality improvement and patient safety programme.
	c.	Leaders and management are involved and allocate resources for improvement
Standard	**CQI.2:**	**Leaders have oversight function of leading quality improvement activities of the centre.**
Criterion	**a.**	Leaders provide necessary resources required for the quality improvement activities.
	b.	Leaders and management determine the areas for improvement.
	c.	Identified areas are measured and improvement activities are instituted.
Standard	**CQI.3:**	**There is a structured quality improvement programme.**
Criterion	**a.**	The quality improvement programme is developed, implemented and maintained by a multi-disciplinary committee.
	b.	The quality improvement programme is documented which is comprehensive and covers all the major elements related to quality assurance.
	c.	There is a designated individual for coordinating and implementing the quality improvement programme.
	d.	The designated programme is communicated and coordinated amongst all the staff of the centre through appropriate training mechanism.
	e.	The quality programme is responsible for the regular communication of quality issues to all staff
	f.	The quality improvement programme is reviewed and updated at least once in twelve months.
	g.	Regular audits are conducted to ensure continuous compliance of the programme.

	h.	The programme includes documented quality control activity for IVF/ Andrology/ Embryology laboratory.
Standard	**CQI.4:**	**The centre designs clinical and managerial processes to promote quality improvement.**
Criterion	**a.**	The centre has a quality improvement team in place.
	b.	The centre identifies and monitors various processes by data collection to determine if there are areas for improvement.
	c.	The centre identifies and conduct internal audits to identify risks, address key failures and monitor quality improvement progress.
	d.	Individuals with appropriate clinical or managerial experience, knowledge, and skills participate in the process.
	e.	Leadership builds a culture and environment that supports implementation of evidence- based care.
	f.	The centre uses clinical guidelines, protocols or pathways for clinical processes.
	g.	The centre shall identify indicators as per national/international guidelines.
	h.	Leaders obtain feedbacks from patients and staff for quality improvement.
Standard	**CQI.5:**	**There is a structured patient-safety programme in the centre.**
Criterion	**a.**	The centre has a trained patient safety team in place.
	b.	The Patient Safety programme is developed, implemented and maintained by a multi-disciplinary committee and committee meets at least quarterly.
	c.	The patient-safety programme is comprehensive and covers all the major elements related to patient safety and risk management.
	d.	Patient safety programme defines at least sentinel event, adverse event, no-harm event, and near miss event.
	e.	There is a designated trained individual for coordinating and implementing the patient-safety programme
	f.	The designated programme is communicated and coordinated amongst all the staff of the centre through appropriate training mechanism.
	g.	The patient-safety programme is reviewed and updated at least once in twelve months.
	h.	Patient safety programme defines a process for reporting & managing defined events and carries out analysis of the events to identify and implement corrective actions.
Standard	**CQI.6:**	**The centre collects the data, analyse it and use for improvement.**
Criterion	**a.**	The centre collects data on identified indicators to oversee structure, process and outcome. For example, number of oocytes, fertilisation rate, implantation rate, cleavage rate, pregnancy rate, patient satisfaction, staff satisfaction and hand hygiene compliance.
	b.	The data is collected monthly.
	c.	Results are used to evaluate effectiveness of improvement activities.
	d.	The results of data are communicated to all concerned.
Standard	**CQI.7:**	**The centre implements a system for clinical audit.**
Criterion	**a.**	The centre documents a policy and procedure to carry out clinical audit.

	b.	Medical and nursing staff participates in this audit.
	c.	The parameters to be audited are defined by the centre.
	d.	Patient and staff anonymity is maintained
	e.	Management initiates action on the findings to make improvement.
	f.	All audits are documented and remedial measures are implemented
Standard	**CQI.8:**	**The centre defines and analyse sentinel events.**
Criterion	**a.**	The centre defines sentinel events.
	b.	Sentinel events are appropriately analysed when they occur.
	c.	Preventive actions are taken based on the findings of such analysis.

Chapter 6
Patient Assessment and Care (PAC)

Introduction

Patients are made aware of the services being offered through different modes. Processes are defined for various activities including registration, admission, referral and discharge. Patients once taken into the facility either as an out-patient or as in-patient are assessed and re-assessed as per policy for their clinical needs and treatment.

STANDARDS AND CRITERIA		
Standard	**PAC.1:**	**The centre defines and displays its services**
Criterion	**a.**	The centre clearly defines the services being provided and is as per the needs of the community and applicable laws and limitations of centre.
	b.	Services with in scope and out of scope shall be displayed in the centre.
Standard	**PAC.2:**	**The centre has a documented registration and admission process**
Criterion	**a.**	The centre has documented policy and procedure for registration of out-patients, in-patient and emergency patients.
	b.	The staff is aware about the procedure including out-patient, in-patient and emergency patients.
	c.	The procedure includes identifying patients with urgent needs and who require immediate attention and these patients are attended to or treated on priority.
	d.	Patients are accepted only if the centre can provide the services.
	e.	Documented policy and procedure exist to address situation of non-availability of beds.
	f.	A unique number is generated to identify the patient throughout the centre.
Standard	**PAC.3:**	**The centre has adequate mechanism for transfer or referral of patients.**
Criterion	**a.**	The centre has documented procedure that guide the transfer or referral of patients based on their health status and need with referral slip being issued in need.
	b.	The record of transferred or referred patients shall be documented.
Standard	**PAC.4:**	**Initial assessment is conducted of all patients being cared for in the centre.**
Criterion	**a.**	All patients undergo an initial assessment at the earliest as per clinical situation, after admission based on their needs and condition.
	b.	The centre defines the contents of the initial assessment including screening for nutritional needs, pain assessment and allergies.
	c.	The centre shall identify qualified and registered individuals responsible for the assessment of patients in accordance with the applicable law and regulation.
	d.	The initial nursing assessment is defined and documented.

	e.	A care plan is prepared based on the initial assessment and signed by the treating clinician for all the patients.
Standard	**PAC.5:**	**Initial assessment is conducted of all patients being cared for in the centre.**
Criterion	**a.**	Patients are reassessed both by clinician and nursing staff if required at appropriate interval based on their clinical status.
	b.	Reassessment determines the course of care for continuation, change in care plan or discharge.
	c.	Staff involved in direct patient care document the findings of reassessment.
Standard	**PAC.6:**	**The centre ensures uniform and continuity of patient care**
Criterion	**a.**	Documented procedure guides the uniform care to patients.
	b.	The care plan for every patient is dependent on their needs at assessment and reassessment.
	c.	The care plan is modified depending on the changes in the patient's condition.
	d.	Qualified individuals provide care to patients based on their licensing, credentials and privileging.
	e.	Patients are monitored during delivery of care and their care is modified when necessary.
	f.	Patients are monitored during delivery of care and their care is modified when necessary.
Standard	**PAC.7:**	**Care rendered to patients is evidence based and documented to ensure uniformity.**
Criterion	**a.**	Current clinical guidelines, protocols, pathways and care bundles are available for the care of patients and regularly updated as per scientific developments.
	b.	These guidelines are used to guide healthcare providers in making appropriate clinical decisions.
Standard	**PAC.8:**	**A documented discharge process exist.**
Criterion	**a.**	The centre plans the discharge process in consultation with the patient and/or family.
	b.	Documented process consists of coordination between various departments and units.
	c.	A discharge summary is provided to all patients with one copy saved in file at centre.
	d.	The turn-around time for discharge is defined and monitored for improvement.
Standard	**PAC.9:**	**The centre defines the contents of discharge summary.**
Criterion	**a.**	Discharge summary atleast contains the patient's name, age, partner/spouse name, address of a patient unique identification number, date of admission and date of discharge
	b.	Discharge summary contains the reasons for admission, significant findings and diagnosis and the patient's condition at the time of discharge.
	c.	Discharge summary contains information regarding investigation results, any procedure performed, medication administered and other treatment given.

	d.	Discharge summary contains the reasons for admission, significant findings, diagnosis and the patient's condition at the time of discharge.
	e.	Discharge summary contains information regarding investigation results, any procedure performed, medication administered and other treatment given.
Standard	**PAC.10:**	**Emergency services are provided as per legal framework.**
Criterion	**a.**	Documented policy and procedure guide the management of emergency services and are in compliance with laws.
	b.	Staff is trained to handle emergency patients.
Standard	**PAC.11:**	**The centre has a provision of ambulance service.**
Criterion	**a.**	The centre has appropriate access (owned or outsourced) for ambulance, if required.
	b.	Ambulance is appropriately equipped and meets statutory requirements.
Standard	**PAC.12:**	**The centre has resuscitation services for cardio-pulmonary arrest.**
Criterion	**a.**	Resuscitation services are available to the patient on need basis.
	b.	The centre identifies qualified individuals responsible for resuscitation activities.
	c.	The centre readily makes available medical equipment and medications necessary for resuscitation.
	d.	The centre identifies a designated area for storage of emergency medication.
	e.	All such events are recorded, post-event analysis is done and measures taken for improvement.
Standard	**PAC.13:**	**The centre defines policy and procedure for nursing care.**
Criterion	**a.**	The centre has a documented policy which defines minimum documentation by nurses and also based on the patient's clinical condition.
	b.	Care provided by nurses is documented in the patient record and must contain nursing initial assessment, vital signs and drug/medication chart.
	c.	The nursing handovers shall be documented.
Standard	**PAC.14:**	**The centre provides appropriate diagnostic laboratory and imaging services**
Criterion	**a.**	The centre provides diagnostic laboratory and imaging services essential for the scope of ART.
	b.	Appropriate diagnostic laboratory and imaging services not available are outsourced based on a defined quality management system
	c.	The centre maintains record of all patients undergoing diagnostic services.
	d.	The centre ensures quality of results of these services.
	e.	The centre ensures safety of patient and staff while providing such services
	f.	The centre complies with applicable regulatory requirements for these services.

Chapter 7
Patient Rights and Education (PRE)

Introduction

Patient is in the centre of the care being provided in an ART centre. It is therefore important that patients' rights are documented and known to patients. It is also important to provide education to patients related to their care. Better patient satisfaction or outcome is achieved when patients are adequately informed about their care, their rights are respected and they are involved in the decision-making process.

STANDARDS AND CRITERIA		
Standard	**PRE.1:**	**The centre protects and promotes rights of patients and family.**
Criterion	**a.**	Patient rights are defined, documented and displayed in minimum bilingually (English and Local language)
	b.	Centre leadership implements patient and family rights as identified in laws and regulations
	c.	Patient rights, beliefs and values are informed in a manner and language they understand.
	d.	At all times patient's rights, dignity and privacy is respected.
	e.	Staff including health care practitioners are trained on the processes for and their role in supporting patient and family rights and participation in care.
	f.	Violation of rights is recorded and reviewed for improvement.
	g.	The centre promotes the concepts of patient and family rights by taking measures to increase the awareness and compliance of the same
Standard	**PRE.2:**	**The centre informs patients about their responsibilities while receiving care.**
Criterion	**a.**	Patient responsibilities are identified, documented and displayed in minimum bilingually (English and Local language)
	b.	Patients are informed about their responsibilities in a manner and language they understand
Standard	**PRE.3:**	**The centre identifies and documents the rights of patient supporting individual beliefs, values and privacy.**
Criterion	**a.**	Patient rights include privacy at each steps including while receiving care.
	b.	Patient rights include dignity and respect at each steps including while receiving care.
	c.	Patient rights include confidentiality of information.
	d.	Patient rights include personal safety and security
	e.	Patient rights include giving informed consent
	f.	Patient rights include refusal of treatment after knowing the possible risks.
	g.	Patient rights include documented information on the expected cost of treatment.
	h.	Patient rights include access to his/her medical records in accordance with the applicable law.

	i.	Patient rights include right to complaint and how to voice a complaint as well as participate in the process.
	j.	Patient rights include information on his treatment and healthcare needs.
	k.	Patient rights include patient's request to seek a second opinion within or outside the centre
	l.	Patient rights include respecting any special preferences, spiritual and cultural needs.
	m.	Patient rights include informed consent before the transfusion of blood and blood components, anaesthesia, surgery, initiation of any research protocol and any other invasive/high-risk procedures/treatment and all consent in accordance to ART Rule
Standard	**PRE.4:**	**The centre educates the patient and family to make informed decisions and their involvement in care planning**
Criterion	**a.**	Patients and/or family are informed about the planned care and treatment.
	b.	Patients and/or family are explained about their medicines, consumables, nutrition, and use of medical equipment/ device.
	c.	Patients and/or family are explained about their treatment and/or procedures.
	d.	Patients and/or family are explained about how to continue their care at home after discharge from the centre
	e.	The patient and/or family members are explained about the possible complications.
	f.	The care plan respects and where possible incorporates patient and/or family concerns and requests.
	g.	The patient and/or family members are informed about the results of diagnostic tests and the diagnosis.
	h.	The education material is written and communicated in a language that the patient understands.
Standard	**PRE.5:**	**The centre documents and obtain informed consent from patient and/or family**
Criterion	**a.**	Documented procedure incorporates the list of situations where informed consent is required and adheres to applicable statutory norms.
	b.	Patient informed consent is obtained through a uniformed process defined by the centre and carried out by (an authorized healthcare providers who perform the procedure) in a manner and language the patient can understand.
	c.	Informed consent includes information regarding the procedure/surgery, it's risks, benefits, alternatives and as to who will perform the procedure in a language that they can understand.
	d.	The procedure describes who can give consent when patient is incapable of independent decision making and same is implemented.
	e.	Informed consent is taken by the person performing the procedure.
Standard	**PRE.6:**	**The centre addresses ethical dilemma in a timely manner**
Criterion	**a.**	The centre defines practice for ethical management addressing operational and business issues, including marketing, admissions, consents, transfer, discharge, and disclosure of ownership and any business and professional

		conflicts that may not be in patients' best interests.
	b.	The centre has a documented procedure to receive and address ethical dilemmas in a timely manner.
	c.	The procedure should include patient's decisions not to treat, to withdraw, or discontinue treatment and where treatment is given against the wishes of the patient.
Standard	**PRE.7:**	**The centre has a documented complaint redressal system**
Criterion	**a.**	A documented complaint redressal procedure exists.
	b.	The procedure includes how to receive, investigate and resolve complaints in a timely manner.
	c.	Patient and/or family is made aware of such procedure for making complaint.
	d.	The centre uses the results of investigation to make improvements.

Chapter 8
Medication Management and Safety (MMS)

Introduction

The purpose of Medication Management is to provide a frame work for safe and effective medication management system. Safe and effective medication management includes the processes for procurement, storage, prescribing, transcribing, preparing, dispensing and administration. All processes of Medication Management of the centre comply with rules and regulations of the law of the land.

STANDARDS AND CRITERIA		
Standard	**MMS.1:**	**Documented policy and procedure exist for the management of medication in the centre.**
Criterion	**a.**	Centre defines medication management policy which complies with the applicable laws and regulations.
	b.	Centre defines a procedure to ensure compliance of the policy.
	c.	There is a mechanism in place to inform leaders regarding compliance of the medication management policy and procedures.
	d.	A qualified and registered person as per law directly supervises the activities in each shift the pharmacy, pharmaceutical service and ensures compliance with applicable laws and regulations.
Standard	**MMS.2:**	**The centre develops a drug formulary based on the needs.**
Criterion	**a.**	A list of drugs and medicines based on the need as per scope of its services is developed by collaborative process involving people from different disciplines.
	b.	List of drugs is reviewed and updated at least once in six months.
	c.	Updated Drug formulary is available and assessable to users.
Standard	**MMS.3:**	**A documented procedure exists for safe instilling of diagnostic eye drop.**
Criterion	**a.**	Diagnostic Eye drop is instilled only by trained personnel and only when indicated by the doctor.
	b.	Patient is identified and diagnostic eye drop is verified from the order (for dosage and timing) and physically inspected prior to instilling.
	c.	Diagnostic Eye drop instilling is recorded in the patient records.
Standard	**MMS.4:**	**There is a documented policy and procedure for storage of medications.**
Criterion	**a.**	Medications are stored as per documented policy and procedure including medication stored at patient care units or ambulances.
	b.	The centre ensures that medicines are stored in clean, safe & secure area exclusive for storage of drugs and medicines and in accordance with manufacturer's recommendation.
	c.	A sound inventory control system is implemented throughout the centre by using appropriate tools like ABC, VED, FSN etc.
	d.	High risk, Look-alike and Sound-alike medications are identified and stored

		physically apart (at least not shall in the same drawer, same shelf, same container etc.) from each other throughout the centre.
	e.	Emergency medications are identified and available for use immediately in patient care areas.
	f.	The centre has a process for immediate restocking of emergency medications.
	g.	All stored medicines and reagents used in their preparation are labelled with contents, expiration dates and any applicable warning.
	h.	All expired or contaminated medicines are stored separately according to regulatory requirements to prevent inadvertent dispensing.
	i.	There is a policy on storage of concentrated electrolytes to prevent inadvertent administration.
	j.	The centre has a process for disposing of expired or contaminated medicines and same is documented.
	k.	All medication storage areas, including medication storage areas on patient care units and ambulances (as applicable), are inspected at defined interval as per the centre's policy.
	l.	Medications are protected from loss or theft throughout the centre.
Standard	**MMS.5:**	**There is documented policy and procedure for prescription of medication.**
Criterion	**a.**	Medications are prescribed as per documented policy and procedure ensuring patient safety as per best practice/ guidelines.
	b.	Medication prescription is done as per documented policy.
	c.	Only qualified healthcare providers according to licensure, training or certification can prescribe.
	d.	The centre determines what a complete medication order is but minimally contains patient identification, drug name, dose, frequency and route of administration.
	e.	Medication orders are clear, legible, dated, timed, named and signed.
	f.	Medication prescribed or ordered are documented in patient record and/or inserted in patient record during transfer or discharge
	g.	Documented policy and procedure to be followed for verbal order. This shall also include accurate transcription of verbal order, validation of verbal order and exclusion (where verbal order is not accepted)
	h.	The centre establishes, implements, and trains staff on a process for the safe prescribing, ordering and transcribing of medications.
	i.	The centre has process to intimate the non-availability of medicines in advance (at least day before) to the concerned person.
Standard	**MMS.6:**	**A documented policy and procedure exist for safe dispensing of medications.**
Criterion	**a.**	Documented policy and procedure are implemented for dispensing of medications.
	b.	Preparation of injections, either intravenous or intramuscular, is done using aseptic technique.
	c.	The policy includes a review process for medicine prescriptions before dispensing and it includes right drug, right patient, right dose, right route

		and right frequency.
	d.	High risk medications are verified by two competent persons before dispensing.
	e.	Return of medications to the pharmacy is addressed
Standard	**MMS.7:**	**A documented policy and procedure exist for safe administration of medications.**
Criterion	**a.**	Defined policy and procedure is implemented for administration of drugs including patient's self-administration of medications and own medications brought from outside the centre.
	b.	Medications administration is done only by those permitted by law.
	c.	Patient is identified prior to administration.
	d.	Medication is verified from the order and physically inspected prior to administration.
	e.	Prior to administration, the personal responsible verify and record the drug name, dosage, route and timing.
	f.	Medication administration is recorded in the patient records.
	g.	Guidelines for use of single-use and multidose vials are identified and implemented in the medication process
Standard	**MMS.8:**	**The centre has a system of reporting and analysing near misses, medication errors and adverse drug events.**
Criterion	**a.**	Medication effects on patients are monitored and documented when appropriate
	b.	Near miss, medication error and adverse drug event are defined and reported within a defined time.
	c.	Documented procedure exists to capture near miss, medication error and adverse drug event.
	d.	Data is collected and analysed for such incidents to make improvement.
Standard	**MMS.9:**	**There is a documented policy and procedures for the use of hazardous, narcotic drugs and psychotropic substances.**
Criterion	**a.**	Documented policy for use of such substances exists in consonance with local and national regulations.
	b.	Defined procedure is implemented for the use of narcotic drugs.
	c.	Defined procedure is implemented for the use of psychotropic substances.
	d.	Defined procedure is implemented for the use of hazardous substances.
	e.	Such drugs are stored in a secure manner.
	f.	A record is maintained of usage, administration and disposal of these drugs.
Standard	**MMS.10:**	**Documented policies and procedures guide the use of medical supplies and consumables.**
Criterion	**a.**	There is a defined process for acquisition of medical supplies and consumables.
	b.	Medical supplies and consumables are used in a safe manner, where appropriate.
	c.	Medical supplies and consumables are stored in a clean, safe and secure environment; and incorporating manufacturer's recommendation(s).

	d.	Sound inventory control practices guide storage of medical supplies and consumables.
	e.	The condition of medical supplies and consumables is verified at the time of receipt and regularly as per manufacturer's recommendation and/ centre's policy
Standard	**MMS.11:**	**Medication prescriptions or orders are reviewed for appropriateness**
Criterion	**a.**	The centre defines the prescription policy containing patient-specific information required for an effective review process.
	b.	The centre conduct appropriateness, reviews and audits by person/team competent to do so and are permitted to do so by privileges or job descriptions, and are provided resources to support the review process.
	c.	A structured prescription audit is conducted periodically to ensure implementation of prescription policy.
	d.	The prescriptions audit includes OPD prescription and medication order in IPD.
	e.	Corrective and/or preventive action(s) is taken based on the audit, where appropriate.

Chapter 9
Surgical Care and Safety (SCS)

Introduction

It is important that the ART centre has adequate facility and knowledge to carry out various procedures which are current and based on evidence as far as possible. Different policies and procedures are required to be in place to ensure that procedures being performed provide desired outcomes and care is safe. Surgical procedures adhere to best practices for use of anaesthesia.

STANDARDS AND CRITERIA		
Standard	**SCS.1:**	**Documented procedure exists for the performance of Surgical procedures.**
Criterion	**a.**	Only qualified individuals assess the patients, determine the need for surgery and perform the surgical procedure.
	b.	All phases of surgical care of the patient including pre, intra and post operation are adequately planned and documented.
	c.	The patient & family are educated on the risks, benefits, potential complications, and alternatives related to the planned surgical procedure.
	d.	Informed Consent is obtained by the person performing the procedure/ operating surgeon prior to the procedure/ surgery adhering to statutory norms.
	e.	Patients are monitored intra and post operatively as determined by the condition and surgical procedure. And monitoring is documented in the patient records.
	f.	The surgical record and report, operative progress note is available immediately after surgery before the patient is transferred to the next level of care
Standard	**SCS. 2:**	**Documented procedure exist for use of blood and blood-products.**
Criterion	**a.**	Centre complies with laws, regulations and best practices regarding provisioning of blood and blood products.
	b.	Monitoring during and after administration of blood & blood products is documented.
	c.	Timeframe for availability of blood and blood products is defined and implemented.
	d.	The patient education includes the need for, risks and benefits of, and alternatives to blood and blood-products use if any.
Standard	**SCS.3:**	**ART procedures are carried out as per documented policies and procedures.**
Criterion	**a.**	The centre has a list of ART procedures as per defined scope of services.
	b.	The centre has documented policies and procedures for carrying out listed ART procedures.
	c.	The centre has documented procedures for Andrology, Embryology and IVF laboratory.
	d.	The policy & procedure must include provision for unique identification of

		patients and their reproductive cells and tissues, while retaining patient confidentiality
	e.	The policy & procedure should also be in place for dealing with non-compliances, emergencies, errors, adverse events and complaints.
	f.	The results of procedures and treatments performed are documented in the patient's medical record
	g.	Quality Control records should be maintained and reviewed, including documentation of results and any corrective and preventive action
Standard	**SCS.3:**	**Patient care after surgery or procedure is planned and documented**
Criterion	**a.**	The postsurgical and/or post procedural care provided by medical, nursing, and others meet the patient's immediate post-surgical needs.
	b.	The continuing postsurgical plan of care is documented in the patient's medical record by the surgeon.
	c.	When indicated by a change in the patient's needs, the postsurgical plan of care is updated or revised based on the reassessment of the patient by the health care practitioners
	d.	The centre develops and implements documented criteria describing early warning signs of a change or deterioration in a patient's condition and when to seek further assistance.
Standard	**SCS.4:**	**The centre follows a documented procedure for surgical safety**
Criterion	**a.**	Documented policy and procedure guide surgical safety.
	b.	The centre uses a checklist (e.g. WHO surgical safety checklist) to document the process and the same is documented and recorded in the patient's records.
	c.	All members of the surgical team are involved in the time out process.
Standard	**SCS.5:**	**Documented policy and procedure is used for administration of anaesthesia/ moderate sedation.**
Criterion	**a.**	Administration of anaesthesia/ moderate sedation is used as per applicable local and national laws, and regulations.
	b.	Only Qualified Healthcare professional conduct pre anaesthesia and pre induction assessments and administer anaesthesia/ sedation for patients that require anaesthesia or moderate sedation.
	c.	The Healthcare professional performing the procedure and administering the sedation/anesthesia shall be different.
	d.	Informed Consent is obtained before anesthesia and/or procedural sedation by anesthetist
	e.	Each patient's anesthesia care is planned and documented, and the anesthesia and technique used are documented in the patient's medical record.
	f.	Patients are educated on type of anaesthesia, technique, risks and benefits before administration of anaesthesia/ sedation.
	g.	Physiological status of patients is monitored during anaesthesia and sedation. Intra-procedure monitoring includes at a minimum the heart rate, cardiac rhythm, respiratory rate, blood pressure, oxygen saturation, and level of sedation.
	h.	Each patient's post anesthesia status is monitored and documented, and the

		patient is discharged from the recovery area by a qualified healthcare professional or by using established criteria (e.g. Aldrete or modified Aldrete score)
	i.	The centre has necessary, equipment, and supplies to safely administer anaesthesia / sedation and deal with potential or unintended outcomes.
Standard	**SCS 6:**	**Documented policy and procedure exist for any research activity.**
Criterion	**a.**	Documented policy and procedure address any research activity carried out in the centre in compliance with applicable regulatory, national and international guidelines.
	b.	Appropriate Ethics Committee oversees all research activity.
	c.	Patient's informed consent is taken before enrolling into research/ clinical trial.
	d.	Patients are informed on expected benefits, potential discomforts & risks, their right to withdraw from research at any stage.
	e.	As appropriate, patients and families are identified and informed about how to gain access to clinical research, clinical investigations, or clinical trials relevant to their treatment needs.
	f.	Human subjects research, when provided within the centre, is guided by laws, regulations, and documented policies & procedures.
	g.	The leaders recognize and establishes mechanisms for compliance with all regulatory and professional requirements related to research

Chapter 9
Hygiene and Infection Control (HIC)

Introduction

Changing technology and disease profile continue to present new challenges for infection prevention and control within healthcare facilities. Patients are at risk of developing healthcare associated infections because of decreased immunity among patients; the increasing variety of medical procedures and invasive techniques creating potential routes of infection; and the transmission of drug-resistant bacteria among crowded CENTRE populations, with poor infection control practices. Healthcare associated infections are among the most common complications affecting patients.

STANDARDS AND CRITERIA		
Standard	**HIC.1:**	**The centre has a comprehensive hygiene and infection control programme.**
Criterion	**a.**	There is a hygiene and infection control programme that covers clinical and non-clinical areas.
	b.	Hygiene and infection control programme is managed by a trained individual.
	c.	Centre has an Infection Control committee.
	d.	Centre has infection control officer for coordination of infection control activities.
	e.	The infection prevention and control programme is reviewed and updated at least once a year.
	f.	The infection control programme includes infection control policies and procedures for clinical and non-clinical areas.
	g.	The infection control programme includes proper waste disposal including medical and non-medical waste.
	h.	The infection control programme includes cleaning, disinfection and sterilisation activities.
	i.	The programme includes hand hygiene programme
	j.	The programme includes prevention of cross contamination of stored semen, embryo and gamete
	k.	Infection Control Programme includes steps for pest control
	l.	The centre provides adequate and appropriate resources for infection prevention and control
Standard	**HIC.2:**	**There is documented process to ensure infection control in medication management.**
Criterion	**a.**	The centre ensures pharmacy and patient care units or ambulances where medicines are kept is clean.
	b.	There is a procedure for cleaning of refrigerators where drugs are kept and a cleaning log is maintained.
	c.	The standard hand hygiene practices are followed while handling medication.
	d.	There is a procedure for cleaning of medication shelves, floors and other areas.
Standard	**HIC.3:**	**There is documented process to ensure infection control in kitchen area.**

	a.	Kitchen area is appropriately zoned
	b.	There is a procedure for cleaning of the kitchen.
	c.	There is a hand wash basin facility in the kitchen.
	d.	Foods are stored at appropriate temperature and in appropriate containers.
	e.	There is a procedure of monitoring foods that are kept in refrigerators to ensure a first in first out policy.
	f.	The centre shall ensure documented policy on food supply and use in case of non-availability of kitchen services
	g.	A focal person oversees the quality of in-house and outside food supplies.
Standard	**HIC.4:**	**There is documented process to ensure infection control in laundry.**
Criterion	**a.**	The laundry has separate area for handling dirty, soiled and clean linen.
	b.	Linen soiled with blood or body fluids are handled with appropriate Personal Protective Equipment eg gloves, face masks or aprons.
	c.	Soiled linen is collected from clinical areas in covered leak proof containers.
	d.	Washed and ironed linen are neatly folded and stored in appropriate areas.
	e.	The laundry is clean and safe, and detergents are labelled.
Standard	**HIC.5:**	**There is documented process to ensure infection control in sterilisation unit.**
Criterion	**a.**	The organisation provides adequate space and appropriate zoning with unidirectional flow for sterilisation activities
	b.	The unit has identified area for cleaning of instruments with traffic control in place to avoid cross-contamination.
	c.	There is a process for decontamination of dirty instruments immediately after use or before they are cleaned using appropriate disinfectants.
	d.	There is a procedure for cleaning instruments and other items including the use of personal protective equipment, and appropriate cleaning materials.
	e.	The area for wrapping and packaging of instruments is adequate, clean and safe.
	f.	The process of packaging of instruments and other items to be sterilized is performed properly and in accordance with the centre policy.
	g.	The process of loading the autoclave is done appropriately and according to manufacturer's instructions.
	h.	The sterile storage area should be separate from sterilisation area
	i.	Regular validation tests for sterilisation are carried out, documented and reviewed.
	j.	The process of recall is documented and implemented in the sterilisation unit. The staff must be aware of the process for the same.
Standard	**HIC.6:**	**The centre has a documented process to ensure infection control in Operation theatre.**
Criterion	**a.**	The operation theatre is appropriately zoned.
	b.	There is a procedure for cleaning and the log is maintained
	c.	There is a procedure for disinfection and sterilisation and the log is maintained
	d.	Regular validation tests for sterilisation in operation theatre are carried out, documented and reviewed.
	e.	Documented verification and validation reports shall be available in the operation theatre
Standard	**HIC.7:**	**The centre has a documented process to ensure infection control in**

		laboratory area.
Criterion	**a.**	The laboratory area is appropriately zoned.
	b.	There is a procedure for cleaning and the log is maintained
	c.	There is a procedure for disinfection and sterilisation and the log is maintained
	d.	Regular validation tests for sterilisation in laboratory is carried out, documented and reviewed.
	e.	Documented verification and validation reports shall be available in the laboratory.
Standard	**HIC.8:**	**The centre has a documented policy on biomedical waste segregation and disposal in accordance with laws.**
Criterion	**a.**	A documented policy on handling biomedical waste exists.
	b.	Waste segregation is performed at the site of generation.
	c.	Appropriate personal protective equipment are available and used when handling waste.
	d.	The centre identifies a centralised area for collection of medical and non-medical wastes in accordance with laws.
	e.	The centralised area for waste collection is covered and free from rodents and flies.
	f.	There are puncture proof sharps boxes for disposing of needles, syringes and surgical blades.
	g.	There is a process of safe disposal of biomedical waste within the centre and to final waste disposal point.
Standard	**HIC.9:**	**The centre has system of use of Personal Protective Equipment (PPEs).**
Criterion	**a.**	The centre must make PPEs (e.g. gloves, protective eye wear, mask, apron, gown, boots/ shoe covers, cap/ hair cover) available at all times.
	b.	Staff must be regularly trained and educated on the appropriate use and disposal of PPEs
	c.	Support staff including medical aides, cleaners, and laundry staff must wear PPEs in situations where they may have contact with blood, body fluids, secretions and excretions.
	d.	PPEs should be worn by Health Care Workers, who handle patient specimens.
Standard	**HIC.10:**	**The centre has a policy on hand hygiene.**
Criterion	**a.**	The centre implements a system of hand hygiene practices
	b.	Healthcare workers wash or decontaminate hands using a plain soap, antimicrobial agent, such as an alcoholic hand rub after dealing with blood/ body fluids/ secretions/ excretions/ contaminated items, and in between contacts with patients.
	c.	Staff is trained on hand hygiene practices on regular basis
	d.	Hand Hygiene practices are monitored, documented and reviewed.
Standard	**HIC.11:**	**The centre has a policy and procedure for general cleaning and disinfection.**
Criterion	**a.**	Clinical and non-clinical areas are kept clean and records are maintained
	b.	There is a process to ensure proper preparation and use of disinfectant.
	c.	The centre performs surveillance to capture and monitor infection prevention and control data
	d.	The scope of surveillance incorporates tracking and analysing of infection risks, rates and trends.

	e.	Staff is trained on Infection Prevention and control activities

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