



POLICY – INCIDENT MANAGEMENT

1. INTRODUCTION

City Fertility and their day hospitals aim to provide compassionate and exceptional patient care in a safe environment for all couples and individuals. As such the principles of risk management are applied to every step of every procedure and a clear framework for incident management has been established.

2. OBJECTIVE

The objective of this policy is to ensure that all staff are familiar with the incident management framework and are empowered to openly and effectively communicate with patients, other staff and any persons who enters a City Fertility clinic, consult room, office procedure centre or day hospital should an incident occur. There are defined responsibilities for all City Fertility staff as well as City Fertility Clinicians and Medical Officers that include the identification, reporting, investigation and monitoring of incidents.

3. SCOPE

This policy applies to all City Fertility staff, City Fertility Clinicians, Medical Officers and any other contractor or stakeholder present at the time of an incident.

4. REFERENCES

RTAC Code of Practice

POL-CO-17 HSQ Legal and other requirements and references overview
POL-CH-94 Policy – Corporate Governance
POL-CH-111 City Health By-laws for Medical Officers Victoria
POL-CH-110 City Health By-laws for Medical Officers New South Wales
POL-CH-109 City Health By-laws for Medical Officers Queensland

POL-NU-1 Policy – Open Disclosure
POL-CO-4 Policy – Risk Management
PRO-NU-CF-21 Procedure – Serious Notifiable Events
DOC-CL-14 Form – Incident Notification
DOC-HS-1 Form – Safety Incident

5. DEFINITIONS

Risk Management – identification and control of hazards as well as analysing of data and monitoring of results in relation to control measures.

Open Disclosure – when a patient safety incident occurs, acknowledgement and timely communication including an apology, followed by ongoing support of the patient and their carer to resolve the incident.

6. POLICY

6.1. Key elements

Consultation

Patients of City Fertility and their day hospitals will be consulted with on all decisions relating to their care before, during and after all Assisted Reproductive Technology (ART) treatment. Patients will receive information in a way that it is clear, concise and understood such that informed consent can be obtained. This must always include a discussion of the risks, potential incidents that may occur and what they, as a patient, should do if an incident occurs. Furthermore, should an incident occur during



any ART procedure or as a direct result of an ART procedure, City Fertility will communicate about that incident in accordance with the Policy – Open Disclosure.

Environment

The Work Health & Safety Acts and Regulations require designers to ensure that buildings or structures used as a workplace are designed to be safe and without risks to health. This includes provision of safely designed premises, work environments, facilities, fixtures, fittings, equipment and systems of work that do not create, contribute to or exacerbate the risk of an incident occurring. City Fertility will only engage reputable companies with a proven record within construction of health care facilities.

Instruction, education & training

City Fertility supports prevention of incidents through:

- Quality and safety culture lead by the Board
- Robust risk management undertaken by the Audit and Risk Committee (ARC)
- Defined roles and responsibilities for all City Fertility staff, Clinicians & Medical Officers, stakeholders and patients
- Making safety a priority in every action, in every day by providing sufficient instruction, education and training to staff in relation to incident management.

Responsibilities

The Board

The City Fertility Board as defined in the Policy – Corporate Governance has a commitment to delivery of safe, high quality care, that is evident through an effective quality and safety culture. All necessary action, including but not limited to provision of resource – whether capital expenditure or personnel, time, information and oversight will be taken to ensure that the risks of any incident happening are removed or reduced and that in the event of an incident a framework exists to effectively and efficiently manage the incident.

Audit and Risk Committee

The City Fertility ARC are responsible for ensuring that risks are identified and assessed that may lead to safety incidents as per Policy – Risk Management. Furthermore, the ARC will determine the mechanisms to control the risks such as preventative maintenance, approved supplier lists, critical limits and documentation.

The ARC will provide the National Management Team with ongoing directives in relation to establishing and implementing control mechanisms for risk management. The ARC will report on an annual basis, or where deemed necessary based on risk assessment, to the Board any new or emerging risks as well as the analysis of incident management.

National Management Team and General Managers

City Fertility National Management Team and General Managers are responsible for ensuring that control mechanisms are established within the quality and safety management system and that critical limits are implemented, complied with, reviewed, analysed, reported on and continually improved within clinical and day hospital settings.

The National Management Team and General Managers are also responsible for reporting any risk that they identify to the ARC.

The National Management Team and General Managers will ensure staff are adequately instructed, educated and trained and in relation to incident management. Where necessary, General Managers will ensure staff are supervised in order to perform their work in a manner that will minimise the risk of incident occurring. The General Manager will include incident management in clinic meetings, specifically, review or investigation of incidents that have occurred as well as any corrective or



preventative actions that must be completed in order to facilitate continual improvement of clinical procedures.

The National Compliance Manager, together with the General Manager of the day hospitals will review, analyse and report the incident data.

General Managers will follow up, complete and close the incident on the City Fertility Database. The National Compliance Manager will, where required under the Reproductive Technologies Accreditation Committee Standard (RTAC), report any patient incident to the relevant authorities.

Clinician

The onboarding and orientation process for new Clinicians & Medical Officers is such that all risks associated with ART are minimised. New Clinicians & Medical Officers are required to be deemed competent first with the procedures of the clinic, then theoretically through consultations with patients, then under supervision and finally must be authorised to practice with City Fertility by the Medical Director and or Medical Advisory Committee.

Clinicians & Medical Officers will comply with a Code of Conduct as outlined in City Health By-laws for Medical Officers Victoria, NSW and QLD and in all instances use conservative management of patients to ensure that the risks associated with ART procedures are reduced. Clinicians & Medical Officers will discuss and provide written and or electronic information on the risks of ART procedures with patients and will specifically communicate about what an incident is and what the patient or carer can do if they are worried at any time about their health or safety.

Clinicians & Medical Officers are responsible for any incident involving their patient either within or outside of clinical hours. Clinicians & Medical Officers must be contactable or provide alternative contact details to the patient for use if an incident occurs.

If an incident occurs, a Clinician will communicate with the patient about that incident in accordance with the Policy – Open Disclosure.

Clinicians must communicate any incident that occurs outside of hours with the relevant Nurse Coordinator. Clinicians & Medical Officers must complete any and all documentation associated with investigation and reporting of incidents; the Medical Director will be responsible for reviewing any clinical incident.

Staff

Staff will take reasonable care of their own health and safety and the health and safety of other persons (employees and others) who may be affected by their acts or omissions at the workplace. Staff will comply with all workplace health and safety policy as well as clinical policy and procedures in relation to patient health and safety; will obey any health and safety directive given to them; will partake in training as they are required; and will be involved in clinic meetings discussing health and safety matters.

Staff are also responsible for reporting any risk that they identify to their direct manager. Should a staff member believe that they have not had adequate training to complete a task safely (both for patient and themselves), they should advise their direct manager.

All staff will report to management any incident as soon as they become aware of it, both in relation to patient health and safety and their own personal health and safety. In the instance of a clinical incident the Nurse Coordinator will notify the General Manager and the Medical Director. If an incident occurs, the staff member will communicate with the patient about that incident in accordance with the Policy – Open Disclosure.



Staff will log any incident, either clinical or work health and safety, on the City Fertility Database. Where applicable staff will complete follow up activities with patients and/ or Clinicians & Medical Officers, reporting activities with the General Manager and/ or National Compliance Manager.

Patient

All persons entering a City Fertility Day Hospital are expected to act in a manner that does not negatively impact the health and or safety of themselves or any other.

City Fertility encourages patients to be involved in all decisions relating to their health and safety and provides information on incident management, opportunity to discuss incident management and feedback mechanisms for any opportunities for improvement in relation to incident management.

Patients are expected to contact their Clinician should an incident occur.

Other

City Fertility will provide patients with printed and or electronic information material that covers the risks associated with ART. The risks of ART are also clearly defined in all informed consent documents.

City Fertility will have patient information material in relation to the Australian Charter for Healthcare Rights, Open Disclosure and incident management and reporting visible in all settings.

City Fertility will treat all private and confidential information in accordance with the Privacy Act (Cth) 1988.

6.2. Types of events

Clinical relating to patients

A Serious Adverse Event is any event associated with ART treatment which:

- causes harm, loss or damage to patients or their reproductive tissues;
- causes a significant medical or surgical condition to arise directly from ART treatment;
- results in hospitalisation (>24hours) following, and as a result of, the ART treatment.

A Serious Notifiable Adverse Event is an abnormal unintended outcome associated with ART operations which:

- Might result in the transmission of a communicable disease;
- might result in death or a life-threatening, disabling, or incapacitating condition;
- arises from a gamete or embryo identification error or mix-up;
- might impact safety of people, gametes, embryos, equipment or facilities as a result of a disaster;
- results in a potential or actual breach of legislation.
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Please refer to PRO-NU-CF-21 Procedure – Serious Notifiable Events that outlines cases that shall be classified as a serious notifiable event for both nursing and scientific departments.

Patient Privacy or Confidentiality Breach is any event in which a patient's confidential information becomes known to unauthorised persons without the patient's consent.

Work Health and Safety relating to staff

Immediate treatment as an inpatient	Infection due to – micro-organisms, providing treatment or care to a person, contact with human blood or body substances or needle stick injuries	Exposure to – liquid nitrogen, uncontrolled escape of gas, uncontrolled fire, electric shock, fall from heights, collapse or partial collapse of a structure.
Immediate treatment for – any injury to spine, serious injury to head or eye, serious burn or laceration, loss of body function or amputation		
Medical treatment within 48hrs of exposure to a substance		

6.3. Reporting

All incidents whether clinical or Work Health and Safety will be recorded on the CF Database or Risk Clear Database within 48 hours of the event by a member of staff.

The General Manager will report any adverse events to the Medical Advisory Committee and monitor ongoing statistics about incident data to all staff in monthly clinical meetings.

The National Compliance Manager and General Managers will summarise incident data in an annual management review report.

City Fertility will report all clinical Serious Notifiable Adverse event to the relevant authorities and certifying body within six weeks of the event. City Fertility will also report any Serious Work Health and Safety incident to the relevant authority immediately after becoming aware of the incident.

City Fertility will notify the appropriate authorities (eg. Health Departments, VARTA, RTU, Auditing Body, TGA or HCC) about incidents and adverse events (where relevant).

City Fertility Chief Financial Officer will advise indemnity insurers where there is a risk of legal action as the result of an incident.

6.4. Investigating

The National Compliance Manager and General Manager will instigate a full root cause analysis of any serious incident that occurs within a week of the incident. The outcome of the investigation including any preventative or corrective actions and continuous improvement activities will be disseminated by the General Manager to the Medical Director, MAC and COO.

6.5. Analysing

The National Compliance Manager will review, analyse and report the incident data: year on year, total for the company, clinic by clinic, type of incident, against business KPI and industry standards.

6.6. Monitoring

Compliance with this Policy will be monitored through desktop audits completed by the compliance team.

7. RECORDS

City Fertility and their day hospitals will retain records indefinitely.