Domain 2: Patient Safety and Risk Management

We identify and manage risks to patient safety before they cause harm.

Why This Domain Matters

Specialist practices are not hospitals, but they are not low-risk environments either. Patients undergo procedures under local anaesthetic, receive injectable medications, have biopsies taken, get scoped, have dressings changed, and sit in waiting rooms alongside immunocompromised patients. Some practices operate procedure rooms that are functionally equivalent to a day surgery - but without the governance infrastructure that a day surgery licence requires.

Patient safety in a specialist practice is mostly about systems, not heroics. It is about making sure the right checks happen every time, that equipment works when you need it, that medications have not expired, that someone has actually tested the emergency oxygen, and that your team knows what to do when a patient deteriorates unexpectedly in your rooms.

The practices that have the fewest serious incidents are not the ones with the most experienced clinicians. They are the ones with the most reliable systems.

Quality Statements

2.1 — Clinical Risk Assessment

We identify clinical risks in our practice and manage them systematically.

INDICATORS

2.1.1 The practice has conducted a risk assessment that identifies the key clinical risks associated with the services it provides. This is documented, reviewed at least annually, and updated when services change.

2.1.2 Identified risks are rated for likelihood and consequence and have a nominated owner responsible for managing each risk. High-rated risks have documented mitigation strategies.

2.1.3 The risk assessment considers risks specific to the practice's specialty and setting - for example, procedural complications, diagnostic delay, medication reactions, patient falls, or risks arising from shared tenancy arrangements.

2.1.4 The practice's risk assessment informs its policies, training priorities, and equipment decisions. It is not a standalone document that sits unread in a drawer.

> **SUGGESTED EVIDENCE**
>
> • Clinical risk register or risk assessment document
>
> • Evidence of annual review and updates
>
> • Link between identified risks and corresponding policies or procedures
>
> • Evidence that risk assessment has driven a specific decision or change

2.2 — Infection Prevention and Control

We prevent and control infection through evidence-based practices appropriate to our setting.

INDICATORS

2.2.1   The practice has an infection prevention and control (IPC) policy that is appropriate to the services it provides. A consulting-only dermatology practice has different IPC requirements from a procedural gastroenterology practice, and the policy reflects this.

2.2.2   Standard precautions are followed consistently. This includes hand hygiene, use of personal protective equipment, safe handling of sharps, and management of blood and body fluid exposures. Hand hygiene facilities (or alcohol-based hand rub) are available at every point of care.

2.2.3   Where the practice performs procedures, there are documented protocols for skin preparation, sterile field management, and post-procedure wound care instructions provided to patients.

2.2.4   Reusable instruments and equipment are reprocessed in accordance with AS/NZS 4187 (or the practice uses single-use devices). If reprocessing occurs on-site, the practice can demonstrate compliance with the relevant standard. If reprocessing is outsourced, there is a documented agreement with the provider.

2.2.5   The practice has a process for managing patients who present with, or are known to have, transmissible infections - including scheduling considerations, room cleaning protocols, and staff protection.

2.2.6   Staff who perform exposure-prone procedures have documented evidence of their immunisation status, consistent with the Australian Immunisation Handbook and relevant jurisdictional requirements.

2.2.7   Cleaning schedules are documented and include the frequency of routine cleaning, the products used, and the process for terminal cleaning of procedure rooms between patients.

SUGGESTED EVIDENCE

- Infection prevention and control policy

- Hand hygiene audit results or observations

- Reprocessing logs or outsourced reprocessing agreement

- Staff immunisation records

- Cleaning schedules and product safety data sheets

- Evidence of IPC training for relevant staff

2.3 — Medication Safety

Where we store, supply, or administer medications, we do so safely.

INDICATORS

2.3.1   The practice maintains a current list of all medications held on the premises, including emergency medications, local anaesthetics, procedural sedation agents, and any medications supplied to patients.

2.3.2   Medications are stored in accordance with manufacturer requirements (including cold chain where applicable) and are secured appropriately. Schedule 8 medications, if held, are stored and recorded in compliance with jurisdictional requirements.

2.3.3   Medication expiry dates are checked at defined intervals (monthly as a benchmark). Expired medications are removed and disposed of appropriately.

2.3.4 Where medications are administered in the practice, there is a documented process for patient identification, allergy checking, dose verification, and recording of administration.

2.3.5 The practice has current, accessible protocols for managing adverse medication reactions, including anaphylaxis. All clinical staff can locate and use the anaphylaxis kit, and its contents are checked at defined intervals.

2.3.6 Where the practice supplies medications to patients (e.g., dispensing samples, providing take-home medications post-procedure), there is a record of what was supplied, to whom, and with what instructions.

SUGGESTED EVIDENCE

- Medication inventory list

- Cold chain monitoring records (if applicable)

- Expiry date checking log

- Medication administration records

- Anaphylaxis kit contents checklist with check dates

- Schedule 8 register (if applicable)

- Records of medications supplied to patients

2.4 — Equipment and Device Management

Our clinical equipment is safe, maintained, and fit for purpose.

INDICATORS

2.4.1 The practice maintains a register of all clinical equipment, including the device type, serial number, date of purchase or lease, and servicing schedule.

2.4.2 Equipment is serviced, calibrated, and tested in accordance with manufacturer recommendations and relevant Australian Standards. Service records are retained.

2.4.3 Staff who operate clinical equipment are trained in its correct use and can demonstrate competency. Training records are kept.

2.4.4 The practice has a process for managing equipment faults or failures, including how to take faulty equipment out of service, how to report the fault, and what interim arrangements apply while equipment is unavailable.

2.4.5 The practice monitors TGA safety alerts and recall notices relevant to the equipment and devices it uses, and can demonstrate that it has acted on any applicable alerts.

2.4.6 Single-use devices are not reprocessed or reused unless the practice holds a TGA-approved reprocessing arrangement.

- Equipment register

- Service and calibration records

- Staff training and competency records

- Process for managing equipment faults

- Evidence of monitoring TGA alerts (e.g., subscription to TGA email alerts, log of actions taken)

2.5 — Emergency Preparedness

We are prepared to respond to clinical emergencies that could reasonably occur in our practice.

INDICATORS

2.5.1 The practice has identified the clinical emergencies that could reasonably occur in its setting - based on the patient population, the procedures performed, and the medications administered. A practice that performs procedural sedation has different emergency preparedness requirements from a practice that provides consulting services only.

2.5.2 Emergency equipment is available, accessible, and appropriate to the identified risks. At a minimum, this includes a means of calling for external emergency assistance (000), oxygen delivery equipment (where procedures are performed), a basic airway management kit, and an anaphylaxis kit.

2.5.3 Emergency equipment is checked at defined intervals (monthly as a benchmark) and after every use. Check records are maintained.

2.5.4 All clinical staff have current Basic Life Support (BLS) certification. Where the practice performs procedures that carry a risk of cardiopulmonary compromise, at least one practitioner present during procedures holds Advanced Life Support (ALS) certification.

2.5.5 The practice conducts or participates in emergency response drills or simulations at least annually. Drills are documented and any lessons learned are acted upon.

2.5.6 The practice has a documented arrangement for patient transfer to a hospital in the event of a clinical emergency, including the nearest appropriate facility, the transfer process, and communication responsibilities.

SUGGESTED EVIDENCE

- Emergency risk assessment

- Emergency equipment inventory and check records

- Staff BLS/ALS certification records

- Emergency drill records and improvement actions

- Patient transfer protocol or arrangement

- Signage displaying emergency contact numbers

2.6 — Safe Management of Procedures

Where we perform procedures in our rooms, we apply appropriate safety standards.

INDICATORS

2.6.1 The practice has defined which procedures are performed on-site, and has assessed the suitability of its facilities, equipment, and staffing for each procedure type.

2.6.2 Pre-procedure processes include patient identification, confirmation of the planned procedure (including site and side where relevant), verification of informed consent, and a check of relevant allergies, medications, and comorbidities.

2.6.3 For procedures that carry a risk of wrong-site or wrong-patient error, the practice uses a procedural safety checklist or time-out process.

2.6.4 The practice has documented post-procedure care instructions that are provided to patients, including expected recovery, warning signs, and how to contact the practice or seek emergency care after hours.

2.6.5 The practice has defined patient selection criteria for in-rooms procedures - including circumstances where a procedure should be performed in a day surgery or hospital setting instead, based on patient complexity, anaesthetic requirements, or procedural risk.

2.6.6 Procedure outcomes, including any complications, are recorded in the patient's clinical record.

SUGGESTED EVIDENCE

- List of procedures performed on-site with suitability assessment

- Pre-procedure checklist or time-out process

- Patient information and post-procedure care sheets

- Patient selection criteria for in-rooms vs. hospital procedures

- Complication records in clinical notes

2.7 — Workplace Health and Safety

We provide a safe working environment for our staff, contractors, and visitors.

INDICATORS

2.7.1 The practice meets its obligations under the relevant jurisdictional Work Health and Safety Act. A person has been nominated with responsibility for WHS within the practice.

2.7.2 Workplace hazards are identified and managed. This includes manual handling risks, sharps injuries, exposure to hazardous substances (including sterilising chemicals and cytotoxic agents where applicable), slip and trip hazards, and risks of occupational violence.

2.7.3 Staff have access to appropriate personal protective equipment, and its use is consistent with practice policy and the nature of the task.

2.7.4 There is a process for reporting and recording workplace injuries and incidents, including sharps injuries and blood or body fluid exposures. Post-exposure protocols are documented and accessible.

2.7.5 First aid supplies are available and maintained. At least one staff member holds a current first aid certificate.

2.7.6 The practice has considered security risks appropriate to its setting, including after-hours access, duress arrangements for staff, and management of aggressive or distressed patients.

SUGGESTED EVIDENCE

- WHS risk assessment or hazard register

- Workplace injury and incident records

- Sharps injury and exposure protocol

- PPE availability and usage records

- First aid kit contents and check records

- Security risk assessment or measures

Self-Assessment Summary

Ref	Indicator
2.1.1	Clinical risk assessment conducted
2.1.2	Risks rated with owners and mitigations
2.1.3	Specialty-specific risks considered
2.1.4	Risk assessment informs decisions
2.2.1	IPC policy appropriate to services
2.2.2	Standard precautions followed
2.2.3	Procedural protocols documented
2.2.4	Instrument reprocessing compliant
2.2.5	Transmissible infection management
2.2.6	Staff immunisation documented
2.2.7	Cleaning schedules documented
2.3.1	Medication inventory maintained
2.3.2	Medications stored and secured
2.3.3	Expiry dates checked regularly
2.3.4	Administration process documented
2.3.5	Anaphylaxis protocols and kit current
2.3.6	Medications supplied to patients recorded
2.4.1	Equipment register maintained
2.4.2	Equipment serviced per schedule

Ref	Indicator
2.4.3	Staff trained on equipment
2.4.4	Equipment fault management process
2.4.5	TGA alerts monitored
2.4.6	Single-use devices not reused
2.5.1	Emergency risks identified
2.5.2	Emergency equipment available
2.5.3	Emergency equipment checked regularly
2.5.4	Staff BLS/ALS certification current
2.5.5	Emergency drills conducted annually
2.5.6	Patient transfer arrangement documented
2.6.1	In-rooms procedures defined and assessed
2.6.2	Pre-procedure verification process
2.6.3	Procedural safety checklist used
2.6.4	Post-procedure care instructions provided
2.6.5	Patient selection criteria defined
2.6.6	Procedure outcomes and complications recorded
2.7.1	WHS obligations met, person nominated
2.7.2	Workplace hazards identified and managed
2.7.3	PPE available and used
2.7.4	Workplace injury reporting process
2.7.5	First aid supplies maintained
2.7.6	Security risks considered

This document is part of the Specialist Practice Quality Framework (SPQF). Visit spqf.au for the full framework, evidence guides, and self-assessment tools.