

Duty of Candour – Policy

Document Details	
Company name:	Medicare Professionals LTD
Title:	Policy
Date last updated:	12/12/2025
Released	Released
Person Responsible	Managing Director
Version:	1
Policy reference number:	MEDP-DOCS-POL



Document History

Version	Date approved	Changes
V1	12/12/2025	Created policy

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POLICY STATEMENT

Medicare Professionals are committed to excellence in service delivery and we believe that Duty of Candour is a core element of this. By embedding transparency, accountability, and continuous improvement into our core operations, we demonstrate to NHS Scotland boards and healthcare organisations that we not only maintain, but enhance patient safety standards in Scotland.

This policy establishes our organisation's commitment to the statutory and professional Duty of Candour as required under the Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016 and the Duty of Candour Procedure (Scotland) Regulations 2018. It outlines our approach to being open and transparent with patients, service users, their families, and our healthcare partners when things go wrong, ensuring we provide the highest standard of care whilst maintaining the trust essential for successful partnerships.

Objectives:

- Comply with all statutory and regulatory requirements under Scottish legislation relating to Duty of Candour
- Meet and exceed Care Inspectorate standards and requirements
- Promote a culture of openness, transparency, and continuous learning
- Ensure patients, service users and families receive appropriate support when incidents occur
- Maintain and enhance trust with our NHS Scotland healthcare partners
- Demonstrate our commitment to safety excellence that justifies our healthcare support model

LEGAL AND REGULATORY FRAMEWORK

This policy operates within the framework of the following Scottish legislation, regulations, and guidance. Understanding and exceeding these regulatory requirements positions us as an excellent partner for healthcare providers in Scotland.

Primary Scottish Legislation:

- Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016 — Part 2, Duty of Candour
- Duty of Candour Procedure (Scotland) Regulations 2018 (SSI 2018/57)
- Public Bodies (Joint Working) (Scotland) Act 2014
- Regulatory Framework: Health and Social Care (Reform) (Scotland) Act 2008
- Adults with Incapacity (Scotland) Act 2000
- Adult Support and Protection (Scotland) Act 2007
- Health and Safety at Work etc. Act 1974 (as applied in Scotland)
- Human Rights: Human Rights Act 1998

Scottish Subordinate Legislation and Directions:

- National Health Service (General Medical Services Contracts) (Scotland) Regulations 2018
- Social Care and Social Work Improvement Scotland (Requirements for Care Services) Regulations 2011
- Regulation of Care (Requirements as to Care Services) (Scotland) Regulations 2002

Professional Standards (Scottish Context):

- GMC: General Medical Council (GMC) Good Medical Practice (2024)
- NMC: Nursing and Midwifery Council (NMC) The Code (2018)
- HCPC: Health and Care Professions Council (HCPC) Standards of Conduct, Performance and Ethics
- SSSC: Scottish Social Services Council (SSSC) Codes of Practice for Social Service Workers and Employers

Regulatory and Oversight Bodies:

- Care Inspectorate
- Healthcare Improvement Scotland (HIS)

- NHS Scotland Quality Strategy
- Scottish Patient Safety Programme (SPSP)

Relevant Scottish Guidance:

- Scottish Government Duty of Candour Guidance for Organisations (2018)
- Healthcare Improvement Scotland
- NHS Scotland Clinical Governance and Risk Management: Achieving Safe, Effective, Patient-Focused Care and Services
- Scottish Patient Safety Programme Standards and Guidance

SCOPE AND APPLICATION

This policy applies across all services delivered by our organisation in Scotland. Our comprehensive scope demonstrates to healthcare partners our policy provides complete coverage across all service areas, ensuring no gaps in Duty of Candour obligations.

Personnel:

- All employees, contractors, and temporary staff working within our services in Scotland
- All healthcare professionals working under our employment or partnership agreements
- Management and leadership teams at all levels
- Board members and non-executive directors

Services Covered:

- All clinical services provided in Scotland
- Support services integral to patient and service user care (facilities, catering, transport)
- Administrative functions affecting patient and service user experience
- Any service where our actions or omissions may impact patient safety or care quality

Incidents Covered (as defined by Scottish Regulations):

- Unintended or unexpected incidents that result in death of a person
- Incidents resulting in permanent harm to a person
- Incidents resulting in harm requiring treatment by a registered health professional
- Near misses with potential for serious harm
- Never Events as defined within Scottish guidance
- Complaints involving safety concerns that meet the threshold for Scottish Duty of Candour
- Safeguarding incidents involving adults at risk or children
- Any incident where a patient, service user or family specifically requests information

DEFINITIONS

The following definitions are based on the Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016 and the Duty of Candour Procedure (Scotland) Regulations 2018.

Duty of Candour

The statutory requirement under Part 2 of the Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016 to be open and honest with individuals and their families when something goes wrong with their care that has the potential to cause, or has caused, harm.

Unintended or Unexpected Incident

Any incident in the course of the provision of a health service or care service that, in the reasonable opinion of a registered health professional or the organisation, was unintended or unexpected at the time it occurred, and has resulted in harm. This definition is drawn from section 21 of the 2016 Act.

Harm

For the purposes of this policy and Scottish regulations, harm means:

- Death of the person
- Permanent harm: any permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removal of the wrong limb or organ
- Harm that requires treatment by a registered health professional (including psychological harm)

Relevant Person

- The patient or service user (if aged 16 or over and has capacity under Scots law)
- A person lawfully acting on the patient's behalf
- Where the patient lacks capacity as defined under the Adults with Incapacity (Scotland) Act 2000, their nearest relative or welfare attorney
- In the case of a deceased patient, their nearest relative or personal representative under Scots law

Candour Conversation

A face-to-face meeting (where reasonably practicable) between appropriately qualified staff and the relevant person to discuss what happened, express sincere regret, and outline next steps in line with Scottish regulatory requirements.

Care Inspectorate

Scotland's national scrutiny and improvement body for social care and combined care services, responsible for regulating and inspecting care services and investigating complaints under the Regulation of Care (Scotland) Act 2001.

Healthcare Improvement Scotland (HIS)

The independent body responsible for inspecting and reviewing NHS Scotland and independent healthcare services. HIS scrutinises NHS boards' compliance with the Scottish Government's Healthcare Quality Strategy.

KEY PRINCIPLES

Openness and Honesty

We commit to being truthful and transparent in all communications with patients, service users, families, and healthcare partners in Scotland. This includes acknowledging when things go wrong and providing clear, understandable explanations, in line with Part 2 of the 2016 Act.

Person-Centred Approach

All Duty of Candour activities prioritise the needs, concerns, and wellbeing of patients and service users and their families, consistent with the Scottish Government's Person-Centred Care approach and the NHS Scotland Quality Strategy.

Timeliness

We respond promptly to incidents, ensuring that candour conversations and written communications occur within the timeframes set out in the Duty of Candour Procedure (Scotland) Regulations 2018, whilst being sensitive to individual circumstances.

Cultural Learning

Every incident is viewed as an opportunity for organisational learning and improvement, contributing to our commitment to continuous enhancement of care quality and alignment with the Scottish Patient Safety Programme.

Just Culture

We foster an environment where staff feel safe to report incidents and participate in candour processes without fear of inappropriate blame, in line with NHS Scotland's Just Culture approach and Healthcare Improvement Scotland guidance.

Partnership Working

We work collaboratively with NHS Scotland boards, Integration Joint Boards, the Care Inspectorate, and Healthcare Improvement Scotland, ensuring seamless Duty of Candour processes that reflect our integrated approach.

ROLES AND RESPONSIBILITIES

Managing Director

- Overall accountability for Duty of Candour compliance across all Medicure Professional's services in Scotland
- Ensuring adequate resources and support for Duty of Candour processes
- Board-level reporting on Duty of Candour performance and learning
- Strategic oversight of organisational culture relating to openness and transparency
- Ensuring annual Duty of Candour reports are published as required by the 2018 Regulations

Clinical Lead

- Clinical leadership for Duty of Candour implementation
- Oversight of candour conversations and clinical decision-making
- Professional guidance to clinical staff involved in incidents
- Liaison with GMC, NMC, HCPC, SSSC, and other professional regulatory bodies as required

Patient Safety Lead/Operations Director

- Operational oversight of all Duty of Candour processes in Scotland
- Coordination of incident investigations and candour activities
- Training and support for staff involved in Duty of Candour
- Monitoring compliance with the Duty of Candour Procedure (Scotland) Regulations 2018
- Reporting to executive leadership on Duty of Candour metrics
- Liaison with the Care Inspectorate and Healthcare Improvement Scotland

Service Line Managers

- Immediate response to incidents within their areas of responsibility
- Ensuring appropriate staff are available for candour conversations
- Local implementation of learning from incidents
- Support for staff involved in Duty of Candour processes

Registered Healthcare Professionals

- Initiating Duty of Candour processes when incidents are identified
- Leading or participating in candour conversations
- Providing clinical explanations to patients, service users and families
- Contributing to incident investigations and learning in line with Scottish requirements

All Staff

- Reporting incidents promptly through established procedures
- Participating in Duty of Candour processes as required
- Supporting patients, service users and families affected by incidents
- Engaging with learning and improvement activities

THE DUTY OF CANDOUR PROCESS

Our process is designed to meet the requirements of the Duty of Candour Procedure (Scotland) Regulations 2018, which set out specific mandatory steps and timescales.

Immediate Response (Within 24 Hours)

Upon identification of a qualifying incident:

Step 1: Immediate Safety Actions

- Ensure immediate patient or service user safety and wellbeing
- Provide necessary medical or care intervention
- Implement risk mitigation measures

Step 2: Incident Notification

- Report through internal incident management system (Datix or equivalent)
- Notify the Patient Safety Lead and relevant managers
- Inform partner NHS Scotland board or Integration Joint Board as per agreement
- Consider external notifications to the Care Inspectorate and/or Healthcare Improvement Scotland
- For Never Events, notify Healthcare Improvement Scotland within the required timescale

Step 3: Initial Assessment

- Determine whether the incident meets the threshold for Duty of Candour under the 2016 Act and 2018 Regulations
- Identify the relevant person(s) to be informed
- Assess immediate communication needs and any support requirements

Notification and Candour Conversation (Within Regulatory Timescales)

The Duty of Candour Procedure (Scotland) Regulations 2018 require the initial notification to be made as soon as reasonably practicable. The following steps must be followed:

Preparation:

- Identify the appropriate registered health professional(s) or responsible person to lead the conversation
- Gather preliminary facts about the incident
- Consider the relevant person's preferences for communication, including language and accessibility needs
- Arrange an appropriate setting and offer independent support to the relevant person

The Candour Conversation:

- Express sincere regret for the incident (an apology is required under the 2016 Act and does not constitute an admission of liability)
- Explain what happened in clear, plain language, avoiding medical jargon
- Acknowledge any harm caused and accept responsibility where appropriate
- Outline immediate actions taken to ensure safety
- Explain the investigation process and indicative timescales
- Invite questions and address concerns
- Offer ongoing support throughout the process

Documentation:

- Record full details of the candour conversation in the patient or service user's records
- Document attendees, key points discussed, and the relevant person's responses
- Note any specific requests or concerns raised by the relevant person

Written Notification (Within Regulatory Timescales)

Following the candour conversation, written notification must be provided to the relevant person and must include:

- A clear account of what happened
- An apology in accordance with the 2016 Act
- Information about the investigation process
- Contact details for ongoing communication
- Information about support services available, including independent advocacy
- Information about the patient's or service user's right to raise concerns with the Care Inspectorate or Healthcare Improvement Scotland

Investigation and Further Communication

Investigation Process:

- Conduct a thorough investigation in line with Scottish Patient Safety Programme and Healthcare Improvement Scotland guidance
- Use Significant Adverse Event Review (SAER) methodology where appropriate
- Engage patients, service users and families in the investigation process where appropriate and in line with 'Getting it right for every child' (GIRFEC) principles where children are involved
- Consider independent review if requested

Ongoing Communication:

- Provide regular updates on investigation progress
- Respond promptly to questions or concerns
- Offer further meetings as needed

Final Communication:

- Share investigation findings and conclusions
- Explain actions taken to prevent recurrence
- Offer a final meeting to discuss outcomes
- Provide information about the Scottish Public Services Ombudsman (SPSO) and other external review options
- Inform the relevant person of their right to contact the Care Inspectorate

Annual Reporting Requirement

In accordance with the Duty of Candour Procedure (Scotland) Regulations 2018, our organisation must publish an annual report on Duty of Candour activity. This report must include:

- The number of times the Duty of Candour procedure was applied during the year
- A description of the actions taken as a result
- Information about staff training on Duty of Candour

The annual report must be published on our website and submitted to the Care Inspectorate.

COMMUNICATION GUIDELINES

Principles of Effective Communication

- **Honesty:** Honesty, provide truthful information about what happened
- **Clarity:** Clarity, use plain English and avoid medical jargon; where possible use the relevant person's preferred language
- **Compassion:** Compassion, show genuine empathy and concern
- **Respect:** Respect, acknowledge the impact on patients, service users and families
- **Active Listening:** Active Listening, allow time for questions and concerns
- **Cultural Sensitivity:** Cultural and Linguistic Sensitivity, consider individual needs; offer Gaelic-medium or BSL communication support where required in Scotland

Apology Requirements

An apology under the 2016 Act means a statement expressing sorrow or regret for the incident. Under the Apologies (Scotland) Act 2016, an apology made in connection with a Duty of Candour process does not constitute an admission of liability in legal proceedings. Staff should be aware of this protection when making apologies.

Communication Channels

- Face-to-face conversations (preferred for initial disclosure as required by the 2018 Regulations, where reasonably practicable)
- Written correspondence for formal notifications
- Telephone follow-up for ongoing updates
- Video calls where face-to-face is not practicable
- Accessible formats including BSL interpretation, Easy Read, and Gaelic where requested

Documentation Requirements

All communications must be:

- Accurately recorded in patient or service user records
- Shared with relevant team members
- Stored securely in line with the UK General Data Protection Regulation (UK GDPR), the Data Protection Act 2018, and NHS Scotland's Records Management Code of Practice for Health and Social Care
- Available for Care Inspectorate and Healthcare Improvement Scotland inspection

TRAINING AND COMPETENCY

Mandatory Training Requirements

All staff must complete:

- Induction: Induction Training, covering Scottish Duty of Candour legislation and regulatory requirements
- Annual Refresher: Annual Refresher, updates on Scottish policy changes, Care Inspectorate guidance, and lessons learned
- Role-Specific: Role-Specific Training, tailored to individual responsibilities within the Scottish healthcare context

Enhanced Training for Key Roles

Healthcare professionals and managers receive additional training covering:

- Advanced communication skills in the Scottish care context
- Conducting difficult conversations and applying the Apologies (Scotland) Act 2016
- Legal and ethical considerations under Scots law
- Cultural competency including Gaelic heritage considerations and diversity in Scottish communities
- Supporting distressed patients, service users and families
- Understanding Care Inspectorate and Healthcare Improvement Scotland inspection processes

Training Content

- Scottish legislative and regulatory framework
- Organisational policy and procedures
- Communication skills and techniques
- Documentation requirements under Scottish Records Management Code
- Available support resources in Scotland
- Case studies and scenario-based learning drawn from Scottish practice

Competency Assessment

- Regular assessment of knowledge and skills

- Observed practice for staff conducting candour conversations
- Feedback and coaching for continuous improvement
- Annual appraisal discussions on Duty of Candour performance

SUPPORT FOR PATIENTS, SERVICE USERS AND FAMILIES

Immediate Support

- Emotional Support: Emotional Support, trained staff available to provide immediate comfort and assistance
- Practical Support: Practical Support, help with immediate needs such as travel, accommodation, or childcare
- Information: Information, clear explanation of what happened and next steps
- Advocacy: Independent Advocacy, information about and assistance accessing independent advocacy services in Scotland

Ongoing Support Services

- Counselling: Counselling Services, access to professional counselling where appropriate
- Independent Advocacy: Independent Advocacy, referral to Scottish Independent Advocacy Alliance (SIAA) member organisations
- PASS: Patient Advice and Support Service (PASS), independent service funded by Scottish Government providing free advice and support; contact details provided to all relevant persons
- Spiritual Care: Spiritual and Pastoral Care, access to chaplaincy services or other spiritual support
- Interpreting: Interpreting Services, professional interpretation for non-English speakers, including Gaelic and BSL
- Communication Support: Communication Support, services for patients and service users with hearing, speech, or learning difficulties

External Resources in Scotland

Information and referrals to:

- Patient support groups and relevant charities in Scotland
- Citizens Advice Scotland for independent advice
- Scottish Public Services Ombudsman (SPSO) for independent review of complaints
- Care Inspectorate, for concerns about regulated care services
- Healthcare Improvement Scotland, for concerns about NHS services
- GMC, NMC, HCPC, or SSSC as appropriate for professional conduct concerns

Long-term Support

- Regular check-ins to assess ongoing needs
- Assistance with continuing care arrangements in liaison with NHS Scotland and Integration Joint Boards
- Support with future healthcare and care decisions
- Memorial services and bereavement support where appropriate

STAFF SUPPORT AND WELLBEING

Immediate Support

Following involvement in a Duty of Candour incident:

- Immediate Debrief: Immediate Debrief, opportunity to discuss the incident with line manager or senior colleague
- Emotional Support: Emotional Support, access to occupational health and counselling services
- Practical Support: Practical Support, adjustment of workload where necessary
- Peer Support: Peer Support, connection with colleagues who have experienced similar situations

Professional Support

- Clinical Supervision: Clinical Supervision, enhanced supervision for staff involved in incidents
- Professional Development: Professional Development, training opportunities to build confidence and skills
- Career Support: Career Support, ensuring career progression is not adversely affected
- Professional Body Liaison: Professional Body Liaison, support with GMC, NMC, HCPC, or SSSC investigations where required

Organisational Support

- Just Culture: Just Culture, commitment to NHS Scotland's Just Culture principles; fairness and learning rather than blame
- Clear Processes: Clear Processes, well-defined procedures to reduce uncertainty and anxiety
- Management Support: Management Support, active involvement and support from the leadership team
- Recognition: Recognition, acknowledgement of staff courage in being open and honest

Resources Available

- EAP: Employee Assistance Programme, confidential counselling and support services
- Occupational Health: Occupational Health, professional health support and advice
- HR: Human Resources, support with employment-related concerns under Scots employment law
- Trade Unions: Trade Union Representatives, access to professional representation
- Peer Support: Peer Support Networks, established support groups within the organisation

DOCUMENTATION AND RECORD KEEPING

Our approach to documentation is designed to meet the requirements of the Duty of Candour Procedure (Scotland) Regulations 2018 and NHS Scotland's Records Management Code of Practice for Health and Social Care.

Documentation Requirements

Incident Records:

- Initial incident report with full details
- Risk assessments and immediate actions taken
- Timeline of events and key decision points
- Staff involved and their roles in the incident

Communication Records:

- Details of all candour conversations including date, time, attendees, and location
- Summary of information provided and questions asked
- Patient, service user and family responses and concerns raised
- Follow-up actions agreed and timescales

Investigation Documentation:

- Investigation terms of reference and methodology (including SAER where applicable)
- Evidence gathered and analysis conducted
- Expert opinions and external input
- Conclusions reached and recommendations made

Correspondence:

- All written communications with patients, service users and families
- Letters, emails, and other formal correspondence
- Records of telephone conversations and informal discussions
- External communications with the Care Inspectorate, Healthcare Improvement Scotland, or other agencies

Record Standards

- Accuracy: Accuracy, all records must be factual, complete, and contemporaneous
- Legibility: Legibility, clear, readable records whether handwritten or electronic
- Timeliness: Timeliness, documentation completed promptly following events
- Security: Security, stored securely in line with UK GDPR and the Data Protection Act 2018
- Accessibility: Accessibility, available to authorised personnel when required

Storage and Retention

- Electronic Systems, secure storage in approved clinical information systems
- Physical Records, locked storage with restricted access
- Retention Periods, in line with NHS Scotland Records Management Code of Practice for Health and Social Care
- Disposal, secure destruction when retention period expires in accordance with Scottish guidance

Access and Disclosure

- Patient/Service User Access, right to access their own records under UK GDPR and the Data Protection Act 2018
- Legal Disclosure, disclosure for legal proceedings as required under Scots law
- Regulatory Access, available for Care Inspectorate and Healthcare Improvement Scotland inspections and investigations
- Internal Access, controlled access for audit, governance, and learning purposes

MONITORING, AUDIT AND REVIEW

Key Performance Indicators

Compliance Metrics:

- Percentage of qualifying incidents where Duty of Candour was triggered appropriately under the 2016 Act
- Timeliness of candour conversations within regulatory timescales
- Completeness of written notifications within statutory timeframes under the 2018 Regulations
- Quality of documentation and record-keeping

Quality Indicators:

- Patient, service user and family satisfaction with Duty of Candour processes
- Staff confidence in conducting candour conversations
- Effectiveness of investigation processes including SAER outcomes
- Implementation of lessons learned and recommendations

Outcome Measures:

- Resolution of complaints related to Duty of Candour
- Care Inspectorate and Healthcare Improvement Scotland inspection outcomes
- Reduction in similar incidents following learning activities
- Cultural indicators relating to openness and transparency

Reporting and Governance

Monthly Reporting:

- Summary of Duty of Candour activity to executive team
- Analysis of trends and patterns
- Progress on improvement actions

Quarterly Board Reports:

- Comprehensive analysis of Duty of Candour performance

- Benchmarking against NHS Scotland and Care Inspectorate standards
- Strategic issues and recommendations
- Patient, service user and family feedback

Annual Report (Mandatory under 2018 Regulations):

- Comprehensive evaluation of Duty of Candour activity during the year
- Review of training programmes and competency frameworks
- Analysis of cultural indicators and staff feedback
- Published on our website and submitted to the Care Inspectorate

Internal Audit

- Regular internal audit of Duty of Candour processes
- Review of compliance with the Duty of Candour Procedure (Scotland) Regulations 2018
- Assessment of documentation quality and completeness
- Evaluation of staff training and competency

External Assurance

- Participation in Care Inspectorate inspection processes
- Engagement with Healthcare Improvement Scotland scrutiny reviews
- Collaboration with Scottish Patient Safety Programme networks
- Participation in NHS Scotland quality improvement initiatives

LEARNING AND IMPROVEMENT

Learning Framework

Individual Learning:

- Personal reflection and development following involvement in Duty of Candour
- Supervision and mentoring to support professional growth
- Access to additional training and development opportunities

Team Learning:

- Team debriefs following significant incidents, including Significant Adverse Event Reviews (SAER)
- Sharing of lessons learned across service areas
- Collaborative development of improved practices

Organisational Learning:

- Systematic analysis of themes and trends across incidents
- Development of organisational policies and procedures aligned with Scottish guidance
- Board-level oversight of learning and improvement

System Learning:

- Contribution to Scottish healthcare learning networks and the Scottish Patient Safety Programme
- Sharing of anonymised case studies and best practice
- Participation in national safety improvement programmes in Scotland

Scottish Adverse Event Review Methodology

Where a Significant Adverse Event Review (SAER) is required, we will follow Healthcare Improvement Scotland's guidance on 'Learning from adverse events through reporting and review'. This includes:

- Establishing a multidisciplinary review team
- Conducting a structured SAER using the approved methodology
- Engaging patients, service users and families throughout the review
- Producing a SAER report with clear recommendations
- Implementing and monitoring agreed improvement actions

IMPLEMENTATION AND REVIEW

Implementation Plan

Phase 1: Policy Launch (Months 1–2)

- Executive team approval and endorsement
- Communication of policy to all staff with reference to Scottish legislative requirements
- Initial training delivery for key personnel covering Scottish Duty of Candour legislation
- Update of relevant procedures and documentation

Phase 2: Training Rollout (Months 2–4)

- Comprehensive training programme for all staff in Scotland
- Competency assessment and certification
- Development of local implementation guides

Phase 3: Full Implementation (Months 4–6)

- Policy fully operational across all Scottish services
- Monitoring and audit systems established
- Annual reporting infrastructure in place

Phase 4: Consolidation (Months 6–12)

- Refinement of processes based on experience
- Advanced training for specialist roles
- Preparation for first annual Duty of Candour report under the 2018 Regulations

Review Schedule

Quarterly Reviews:

- Performance against key indicators
- Staff feedback and suggestions for improvement
- Analysis of incidents and learning opportunities

Annual Review:

- Comprehensive policy effectiveness evaluation
- Stakeholder feedback and satisfaction survey
- Benchmarking against Care Inspectorate and Healthcare Improvement Scotland standards
- Preparation and publication of annual Duty of Candour report

Triggered Reviews:

- Following significant incidents or complaints
- After Care Inspectorate or Healthcare Improvement Scotland inspections
- When new Scottish legislation or guidance is published
- Following organisational restructure or service changes