GIG CYMRU NHS WALES | Ymddiriedolaeth GIG Prifysgol Felindre
Velindre University NHS Trust

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Handling Concerns Policy (Complaints, Claims, Patient Safety Incidents and Duty of Candour)

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1. Executive Summary

This policy has been developed to ensure that Velindre University NHS Trust (the Trust) discharges its statutory responsibilities for the robust, effective, and timely handling of concerns

(complaints, claims, and patient safety incidents) through ensuring organisation wide learning and continuous improvement, in line with the requirements set out within:

- The Health and Social Care (Quality and Engagement) (Wales) Act (2020) (Duty of Quality and Duty of Candour).
- The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) (Amendment) Regulations 2025 ('the regulations') and Listening to People (NHS Wales Complaints, Incidents and Redress) Process
- Equality Act 2010 and Public Sector Equality Duty
- Public Service Ombudsman for Wales Act (2019).
- Duty of Candour Procedure (Wales) (2023).
- NHS Wales National Policy on Patient Safety Incident Reporting & Management (2023)
- Coroners and Justice Act 2009

2. Policy Statement

The Trust fully acknowledges that, as a provider of specialist and complex healthcare services, there will be occasions where things will go wrong.

A number of key changes have been introduced following the implementation of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) (Amendment) Regulations 2025 (“the Regulations”) and the Listening to People (NHS Wales Complaints, Incidents and Redress) Process. These changes require a more compassionate, transparent and responsive approach to concerns handling, including mandatory “Listening Discussions”, clearer communication, improved access to advocacy, and new timeframes for responding to concerns. The overall aim is to transform patient experience by strengthening learning and safety, and by fostering a culture of openness and continuous improvement across NHS Wales, where patients feel heard and genuinely listened to.

As part of the revised process, there is now greater scope for concerns to be settled within Redress, with the financial threshold increased from £25,000 to £50,000. It is anticipated that this change will reduce the number of individuals needing to pursue costly litigation to obtain compensation.

When such circumstances arise, the Trust will ensure that a robust response is provided in accordance with the key principles and statutory requirements of the Health and Social Care Quality and Engagement (Wales) Act 2020, specifically the Duty of Quality and the Duty of Candour, alongside the Regulations and the Listening to People process. The Trust will also act in line with the Equality Act 2010 and the Public Sector Equality Duty. Collectively, these statutory and legislative requirements place a clear obligation on the Trust to handle concerns openly and transparently, with a strong emphasis on learning and continuous improvement to ensure the delivery of safe, timely, effective, efficient, equitable and person-centred care.

2.1 Policy Key Principles

A culture of psychological safety, openness and transparency.	Robust & proportionate Investigations where Early Resolution cannot be reached	Support and wellbeing for staff
Staff equipped with appropriate skill, experience and knowledge in the handling of concerns	Assurance that those raising concerns will be listened to empathetically and receive a compassionate response with engagement throughout the concerns handling process.	Local procedures implemented to support delivery of requirements in line with The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) (Amendment) Regulations 2025 & Listening to People Process
Consistent concern management and reporting systems in place across the Trust.	Continuous improvement through shared learning across the Trust	A bi-lingual service offered through the medium of Welsh.
Provision of a single unified concerns process	Promotion of early resolution to avoid unnecessary escalation and delay.	Timely and consistent approach of concerns in line with the Listening to People Process

3. Scope of Policy

This policy applies to all people engaged to work for the Trust, including host organisations. This includes those employed under a contract of employment, contract for services, and those working under a bank or agency contract.

There is an acknowledgement that the Listening to People Process and the Duty of Candour principles may not apply in their entirety to some hosted organisations. However, the principles and requirements of the NHS Concerns (Complaints and Redress Arrangements) (Wales) Regulations, as amended in 2025, together with the Listening to People Process and Duty of Candour are required to be adopted, where appropriate, as good practice.

The Policy relates to concerns regarding:

- Services, care, and treatment provided by the Trust.
- Services provided by the Trust's employed staff.
- Services provided by independent contractors.
- Services provided by independent or voluntary sector(s) funded by the Trust.

This policy ***does not*** apply to concerns relating to:

- Clinical services provided privately, even when provided on Trust premises.

- Staff contract of employment, e.g., concerns raised though the Respect and Resolution Policy or The Procedure for NHS Staff to Raise Concerns (whistleblowing).
- Public Services Ombudsman investigations.
- Alleged failure of the Trust to comply with a request for information under the Freedom of Information Act (2000).
- Trust disciplinary proceedings arising from the investigation of a concern.
- Civil Proceedings.
- Individual Patient Funding Request (IPFR).
- Police criminal investigations.

If a concern raised is excluded from the scope of the Listening to People Process the Trust will advise the complainant, in writing, as soon as reasonably practicable and provide the reason(s) for the decision as to why the concern will not be dealt with under the Listening to People Process. If any excluded matter forms part of a wider concern, the issues within the scope of the Regulations can be managed under this policy.

4. Aims & Objectives

The Trust is committed to dealing with concerns in a timely, open, honest, transparent, accessible, and equitable manner, with a strong focus upon ensuring that organisational learning and continuous improvement takes place, in accordance with the NHS Wales Duty of Candour and Listening to People Process.

The aim of this Policy is to:

- Ensure the Trust has robust arrangements in place for the effective handling and monitoring of concerns.
- Provide assurance to the Board, and external bodies, of the commitment to implement the requirements of the Listening to People Process in accordance with the NHS (Concerns, Complaints and Redress Arrangements) (Wales) Regulations (as amended 2025), the Health and Social Care Quality and Engagement (Wales) Act 2020,and Duty of Candour Procedure (2023), whilst at the same time ensuring that those with protected characteristics are treated fairly and compassionately, in accordance with the Equality Act.
- Define concern handling roles, responsibilities, and processes.

5. Definitions

Adverse event/incident	An event which causes or has the potential to cause unexpected or unintended consequences involving the safety of the patient, donor, or other persons.
Claim	Allegations of negligence and/or demand for compensation resulting in clinical negligence or personal injury to a service user, member of staff, member of the public or damage to property.
Complaint	Any expression of dissatisfaction about a health service provider’s action or lack of action about the standard of service provided
Complainant	A person who formally raises a concern or grievance either written or spoken or made by any other communication about a health service

	provider's action or lack of action; or about the standard of service provided.
Concern	Any complaint or reported patient/ donor incident to be handled under the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations (amended in 2025) in conjunction with the Listening to People Process.
Duty of Candour	A legal and ethical obligation for health and social care providers and professionals to be open, honest, and transparent with patients (or their families) when things go wrong with their care, especially if it causes or could cause significant harm. This involves telling the person what happened, offering a sincere apology, providing support, and the giving of an explanation of what happened, in addition to taking action to prevent recurrence.
Duty of Quality	A legal responsibility for Welsh Ministers and NHS bodies to secure improvements in the quality of services they provide, supporting the achievement of higher standards and quality of person-centred care services in Wales.
People's Pledge	Sets out a clear, public promise about how people can expect their concerns to be listened to, taken seriously, and responded to across NHS Wales. It explains in plain language the values of fairness, respect, openness and timeliness that underpin the handling of concerns, and the rights individuals have when raising concerns.
Stage 1 (Early Resolution) **Stage 2 (Formal Stage)**	Listening to People Process concerns that could potentially be resolved to the complainant's satisfaction either immediately or within 10 working days of acknowledgement. The Formal Investigation stage may commence if the seriousness of the complaint means that it is inappropriate to deal with it at the Early Resolution Stage. This stage will comprise of advice and support of the steps taken to conduct a formal investigation to determine the root causes and issues, together with any shared learning outcome.
External body/ Agency	An organisation that has an official advisory or regulatory role that has been mandated to regulate the corporate and professional activities of NHS Trusts.
Investigation	A formal and proportionate process of systematically gathering, reviewing, and analysing information to establish the facts, understand contributory factors, and identify learning and improvement following a concern.
Nationally Reportable Incident	A serious event that meets specific criteria for harm or risk, requiring mandatory reporting for learning and oversight, usually resulting from death, serious injury (physical/psychological), neglect, or health and safety failures.
Never Event	Serious preventable safety incident that should never happen, signalling a failure in existing safety systems. These events highlight critical lapses in protocols designed to prevent them, prompting deep system-wide investigations rather than individual blame to improve service user safety.
Near Miss	An unplanned event that didn't cause harm, injury, or damage but had the potential to do so, serving as a critical warning sign for potential future

	accidents by highlighting weaknesses in systems, procedures, or conditions
Qualifying Liability	A liability in tort owed in respect of, or consequent upon, personal injury or loss arising out of or in connection with a breach of duty of care owed to any person in connection with the diagnosis of illness, or in the care or treatment of any patient/ donor/ service user in consequence of any act or omission by a health care professional and which arises in connection with the provision of qualifying services.
Redress	The making of an offer of compensation in satisfaction of any right to bring civil proceedings in respect of a qualifying liability in tort; the giving of an explanation; the making of a written apology and the giving of a report on the action that has been, or will be, taken to prevent similar occurrence
Root Cause Analysis	A process for identifying the basic or causal factor(s) that underlies variation in performance, including the occurrence or possible occurrence of a sentinel event.

6. Roles and Responsibilities

In line with the Regulations the roles and responsibilities for Concerns Handling at the Trust are as follows:-

6.1 Chief Executive Officer

The Trust Chief Executive Officer has overall responsibility for concerns and ensuring investigations are undertaken in an appropriate manner, within appropriate timescales, and is required to ensure that lessons learnt are implemented throughout the Trust to minimise the risk of reoccurrence.

6.2 Responsible Officer

The Responsible Officer is accountable for the effective day to day operation of the Trust's arrangements for dealing with concerns in an integrated and triangulated manner. The Executive Director of Nursing, Allied Health Professionals and Health Science is the Responsible Officer for the Trust and will ensure that arrangements are in place:

- To deal with concerns in accordance with the NHS (Concerns, Complaints and Redress Arrangements) (Wales) Regulations, as amended in 2025, in conjunction with the Listening to People Process;
- To ensure that the principles of the Duty of Candour are applied, where appropriate;
- To allow for the consideration of breach of duty, causation and harm and have provision in place to determine if a qualifying liability exists under the Regulations;
- For incidents, complaints and claims to be dealt with under a unified process.

6.3 Strategic Oversight

A nominated Independent Member is responsible for maintaining a strategic overview of arrangements for ensuring compliance with the Regulations and the Duty of Candour and their operation, including:

- Overseeing how organisational arrangements are operating at a local level;
- Ensuring that concerns are dealt with in compliance with the Regulations;
- Ensuring the Duty of Candour is triggered where appropriate;
- Ensuring arrangements are in place to review the outcome of all investigated concerns and that any failure in the provision of services is identified during the investigation and acted upon, with the focus on learning from the event or issue and, thereafter, making provision for the monitoring of actions, to include monitoring/auditing action plans to prevent risk of safety, harm and reoccurrence. The nominated Independent Member is the individual with responsibility for the Quality, Safety & Performance Committee.

6.4 Corporate Quality and Safety Team

The Corporate Quality & Safety team is responsible for: -

- Ensuring the Trust has appropriate policies, procedures, support, and training in place for the management of concerns across the organisation;
- Delivery of concerns training across the Trust;
- Oversight of the management of concerns. To provide assurance that concerns are recorded, graded, acknowledged, investigated and responded to within the appropriate timeframes and requirements, as set out in the Listening to People Process, in addition to the Trust's own internal standards and requirements;
- Providing assurance that all individuals notifying the Trust of a complaint are offered an in-person (face-to-face, telephone or video call) Listening Discussion;
- Providing assurance that all individuals notifying the Trust of a complaint are proactively offered advocacy in support of raising a concern, in addition to information provided regarding the concerns process, as set out in this policy and the Listening to People Process;
- Ensuring the Trust meets its statutory obligations under the NHS (Concerns, Complaints and Redress Arrangements) (Wales) Regulations, as amended in 2025 and Accessible Communication and Information Standards in Healthcare (WHC/2025/038) to provide information in a way that considers the communication needs of individuals;
- Ensuring the Trust meets its statutory obligations in respect to the management of concerns in the Welsh language and ensuring the provision of Welsh language;
- Providing/sourcing concerns handling, investigation and Datix Cymru training to ensure staff across the organisation are equipped with the knowledge and skills to undertake their role in concerns handling and investigation;
- Overseeing appropriate divisional investigative processes and adherence with national timescales;
- Coordination of investigations where there may have been severe harm or above;
- Leading on all Public Services Ombudsman Wales Reviews / investigations;
- Leading on all Redress processes;
- Leading on all Duty of Candour reporting;
- Leading on National reporting of incidents that meet the threshold, as set out in the National Policy on Patient Safety Incident Reporting;
- Leading on Complex Case Management;
- Provision and undertaking of a comprehensive audit schedule for concerns management;
- Having oversight and dissemination of learning to promote shared learning both within the Trust and, where required, on a wider basis, including nationally;

- Development of Trust-level concerns reporting processes;
- Leading on liaison and meeting requirements of external bodies such as: Coroner's Office; NWSSP Shared Services – Legal and Risk, Police; Citizen Voice Body for Health and Social Care Wales, Llais.
- Representing the Trust at national concerns related meetings.

6.5 Executive Management Board

The Executive Management Board is responsible for the provision of the Trust's unified concerns management process and outcomes, including policies, procedures, and reporting in line with legislative and national requirements; training provision and compliance; identification of and compliance with key performance indicators; meaningful analysis; investigative processes; audit and operational assurance mechanisms; ensuring that remedial action is taken; Duty of Candour mechanisms are in place; and appropriate lessons are identified and shared.

6.6 Quality Safety and Performance Committee

The Quality, Safety and Performance Committee provide assurance to the Trust Board in relation to how the Trust meets its responsibilities under The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) (Amendment) Regulations 2025 in accordance with the Listening to People process and the Duty of Candour Procedure (Wales) (2023), whilst highlighting any exceptions, risks, or potential risks, that might otherwise arise. The Committee's oversight includes ensuring the provision of appropriate training, policies, procedures, and reports in line with legislative and national requirements; identification of and compliance with key performance indicators and analysing key information with a view to addressing risk. The Committee is also responsible for ensuring that processes are in place for concerns investigations to be undertaken and have responsibility for the overall operational assurance mechanisms, including the audit of complaints and incidents and is required to ensure that, where required, remedial action is taken and appropriate learning identified, addressed, and shared with those involved, including sharing learning on an All-Wales basis.

6.7 Integrated Quality & Safety Group

The Trust Integrated Quality and Safety Group (IQSG) provides operational oversight and assurance in relation to the management of concerns across the Trust. This includes reviewing, analysing and triangulating information and outcomes from concerns alongside complaints, incidents, claims, inquests, redress and ombudsman cases to identify themes, trends, risks and areas for improvement. The Group oversees the delivery and monitoring of agreed improvement actions arising from concerns, ensures learning is identified and shared, and confirms that significant issues are appropriately reflected within the Trust's risk register and assurance frameworks. IQSG provides quarterly assurance and escalation reports to the Executive Management Board and the Quality, Safety and Performance Committee, and may commission further analysis, reviews or task and finish work where required to support effective oversight and learning from concerns.

6.8 Corporate Head of Quality, Safety and Assurance

The Head of Quality, Safety and Assurance is responsible. as the Senior Investigations Manager (SIM), for the Trust investigation processes under the NHS (Concerns, Complaints and Redress Arrangements) (Wales) Regulations (amended in 2025), and is responsible for the:

- Oversight of the handling and consideration of concerns in accordance with this policy.
- Auditing Trust and divisional concern handling arrangements.
- Ensuring robust interface arrangements are in place with the divisions to ensure that there is an effective divisional concern handling processes with outcomes.
- Development, integration and embedment of a comprehensive concern investigation and redress system.
- Embedment of a comprehensive Duty of Candour process and procedure.
- Ensuring that the Listening to People process is implemented in accordance with the NHS (Concerns, Complaints and Redress Arrangements) (Wales) Regulations (as amended in 2025).
- Providing assurance to the Executive Management Board and Quality, Safety and Performance Committee on the Trust's concerns management performance and portfolio.
- Ensuring mechanisms are in place for learning and continuous improvement initiatives to be shared across the Trust.

6.9 Service-level Directors (including hosted Organisations)

(Corporate / Divisional Directors, Clinical Directors, Medical Directors)

Service Directors are responsible for ensuring compliance with the Listening to People Process and the Duty of Candour principles and are required to provide assurance on the following: -

- The provision of robust local concern handling arrangements across all service areas within their remit, including that of commissioned services;
- That concerns are managed within required timescales and performance measured against targets;
- That Datix Cymru is the only primary repository for all concerns and associated documentation;
- That a culture of openness, transparency, psychological safety, learning and improvement is promoted, encouraged, and embedded into practice;
- To promote Speaking up Safely and encourage staff members to raise concerns in a ‘psychologically safe’ culture which enables individuals to highlight problems and awareness that requires intervention and the making of suggestions for improvement;
- That employees are appropriately trained in concerns handling training in accordance with their role;
- That employees understand their individual roles and responsibilities in relation to concerns handling;
- To promote cross-divisional and Trust wide approach to concerns handling with appropriate communication, co-ordination, liaison, and reporting;
- To ensure there is adequate and appropriate support available and offered to employees who are involved in, or who are, the subject of a concern;
- To ensure there is availability and release of employees to undergo training in investigations and ensure that employees assigned to investigations can analysis and research information to support the concerns investigation;

- To ensure that all learning that is identified is addressed and shared with those involved and, where required, on a wider basis, with a view to demonstrating improvement and that actions have been taken to minimise risk and prevent re-occurrence of similar events and incidents arising, thereby optimising the function of the quality and safety service;
- To ensure that improvement plans in response to learning from concerns are developed and recorded appropriately in the Trust's Quality & Safety Regulatory Tracker and undertaken within a timely manner.

6.10 Directorate and Departmental Managers

Directorate and departmental managers across the Trust are responsible for ensuring:

- Employees and volunteers are aware of this policy and their roles and responsibilities;
- A culture of openness, transparency, psychological safety, empowerment, learning and improvement;
- That timely concerns handling is promoted, encouraged, and sustained in practice;
- Processes are in place for effective management of concerns to ensure safe discharge of responsibilities in accordance with the Regulations;
- Ensuring all concerns and associated communications and documentation are recorded at the time of reporting and are stored and reported within the Datix Cymru system;
- Provision of robust and timely feedback of concerns outcomes, lessons learnt and improvement opportunities with colleagues;
- Employees are appropriately trained for both concerns handling and the operation of Datix Cymru system;
- Display and provide relevant service user concerns reporting information and signposting within clinical areas e.g. ‘How to raise a concern’ and Llais (Citizen Voice Body for Health and Social Care);
- All identified lessons learnt and improvement actions are addressed, implemented, or escalated as appropriate.

6.11 Breach of Duty & Redress Panel

The Trust's Breach of Duty/Redress Panels are responsible for the consideration and progress of a concern, following investigation, and is responsible for the following: -

- Determination of whether a breach of duty has occurred;
- Determination of whether the breach of duty described has caused harm or potential harm;
- Consideration of engaging an independent clinical expert if a decision on breach of duty cannot be reached;
- Consideration of engaging an independent clinical expert, on a joint basis with the complainant or nominated representative, where causation is in question or further clarity is required to determine the degree of harm, including, where required, condition and prognosis;
- The making a finding/decision in relation to whether a qualifying liability exists (i.e. that harm has been caused from the breach of duty identified);
- Agreement of communication pathways to communicate the decision of the Panel to the individual (or nominated representative) involved and any staff member involved in the concern;

- Agreement of an appropriate award of financial compensation in cases where a Redress remedy applies, or agreement of an appropriate non-financial Redress remedy in cases where compensation is not required;
- Ensuring robust systems capture recorded decision-making processes and outcomes;
- Agreeing suitable regulatory response outcomes, including:
  – A Regulation 26 interim response, where a breach of duty has been identified and potential harm may have been caused;
  – A Regulation 24 outcome, where no breach of duty and no harm has been identified;
  – A Regulation 24 outcome, where a breach of duty has been identified but no harm has occurred;
  – A Regulation 33 final response, where harm amounting to a qualifying liability has been identified following a breach of duty;
  – A Regulation 33 final response, where a breach of duty has been identified but no harm has been identified following investigation under the Redress arrangements.

6.12 Responsibility of all Staff

All staff must ensure:

- Adherence to Trust policy and procedure, the Listening to People process and Duty of Candour procedure;
- All individuals notifying concerns are to be treated with honesty, transparency, respect, and courtesy;
- All concerns are treated confidentially;
- That they understand their individual role and responsibilities for reporting, handling and escalating concerns, incidents, and near misses;
- That they have awareness of available supportive resources;
- Co-operation and engagement in the investigative process;
- All concerns are addressed or escalated at time of reporting;
- That relevant role specific concern management and Datix Cymru training and education is undertaken;
- That all near misses, safety incidents and concerns are reported in line with divisional and departmental processes.

7. Duty of Candour

The Duty of Candour is a legal and ethical obligation for health providers and professionals to be open, honest, and transparent with service users (or their families) when things go wrong. This involves telling the person what happened, offering a sincere apology, providing support, having compassionate discussions, fostering trust and taking action to prevent recurrence and learn from mistakes that are made.

The Trust is responsible for adhering to the legal requirements and will discharge its responsibilities in line with the Health and Social Care (Quality and Engagement) (Wales) Act (2020) and Duty of Candour Procedure (Wales) (2023).

7.1 When does the Duty of Candour apply?

For the Duty of Candour to be triggered the following two conditions must be met:

- **A service user experienced, or may have experienced, unintended, or unexpected harm (physical or psychological harm or in the case of an individual that is pregnant, loss or harm to the unborn child) that is "more than minimal." Although there is no legal definition of minimal harm, in practice this relates to moderate harm or above:**

  ''Moderate Harm: A service user experiences a moderate increase in treatment and significant but not permanent harm, e.g., being given medication, that they have a known allergy to, and this leads to a significant reaction requiring 4 or > days in hospital before recovery.' 'Severe Harm: A service user experiences a permanent disability or loss of function e.g., being given medication, that they have a known allergy to, and this leads to brain damage or other permanent organ damage.'
  'Death: A service user dies e.g., being given medication, they have a known allergy to, and this leads to their death.'

- **The provision of healthcare "was" or "may have been" a factor in the patient or donor suffering that outcome.**

To ensure appropriate consideration of the Duty of Candour requirements the Trust will consider each event upon an individual basis and determine whether a 'notifiable adverse outcome' has occurred, and if the Duty is triggered.

7.2 Requirements of Duty of Candour

The Trust is legally required to adhere to the Duty of Candour principles and will therefore ensure that Duty of Candour Procedure (Wales) 2023 is followed.

7.3 Duty of Candour Procedure

To ensure the Trust fulfils its legal obligations it must have a robust process is in place:

7.3.1 Stage 1 – Rapid Review - Identification of a 'Notifiable Adverse Outcome'

Incidents or concerns graded at moderate harm or higher will receive a rapid review that is undertaken within 48 hours of report to determine whether a notifiable adverse outcome has occurred and if the Duty of Candour is triggered. All rapid reviews and Make it Safe meetings will be recorded in the Datix Cymru system in line with the Trust incident reporting processes.

7.3.2 Stage 2 – 'In Person Notification'

The Trust will ensure that the 'In Person Notification' is undertaken by a suitably trained and skilled individual, either in person, via telephone or audio visually, and completed at the time the Trust first becomes aware the Duty of Candour Procedure has been triggered in line with the Duty of Candour Procedure (2023). A 5 working day window is given before the Stage 1 Listening discussion takes place under the Listening to People Process to allow for acknowledging receipt of the concern, during which it should be considered if the Duty of Candour has been triggered (section 39).

The in-person notification must include:

- Offer of listening discussion
- Clear and compassionate communication, with complex terminology explained
- A meaningful apology:
- Active offers of advocacy and legal support for complainants
- The importance of taking into account any accessibility requirements.
- The encouragement of concerns in the Welsh Language.
- An explanation of the actions and further enquiries that the Trust will undertake to investigate the circumstances of the notifiable adverse outcome.
- Details of the nominated point of contact
- An offer of support and details of any appropriate support information
- If the in-person notification is made later than 30 working days after the Trust first became aware of the notifiable adverse outcome an explanation for the delay should be included.

7.3.3 Stage 3 - Written Communication

The Trust will ensure a formal letter is issued by the Service Director or nominated deputy to the service user/ nominated representative, acting on the individual's behalf within five working days of the “in-person” notification.

The formal letter will include:

- Reiteration of the verbal apology
- Date of notification
- An account of the incident to date and explanation of the actions that the organisation will take as part of the procedure and the investigation
- Point of Contact details
- Details of available support
- If “in-person” notification was later than 30 days after the date on which the incident occurred, an explanation of the reason for the delay is required

7.3.4 Stage 4 - The Review/Investigation

The division, in collaboration with the service user, or nominated representative, will conduct an open, transparent, and proportionate investigation of the incident in accordance with the Regulations and Duty of Candour procedure (2023). Once complete the investigation outcome will be communicated to the service user, or their representative, in accordance with Regulation 24, Regulation 26 and Regulation 33, of the Regulations where the Redress arrangements apply.

7.4 Record Keeping

The Trust will ensure that all correspondence, decisions made, actions and relevant documents are kept in Datix Cymru, in accordance with the Listening to People Process and Duty Candour Procedure. Documentation should include, but is not limited, to:

- Outcomes of Rapid Review Meetings to establish whether the duty has been triggered;
- Notification of the Duty;
- Attempts to contact the service user/nominated representative;

- Any decision by the service user/nominated representative, not to be contacted in relation to the Duty of Candour;
- Investigation of the notifiable adverse outcome, which is undertaken by the Trust, including a final response issued under Regulation 24, interim response issued under Regulation 26 or final response issued under Regulation 33 of the Regulations.

7.5 Consent

The Trust will ensure that relevant consent procedures are followed in line with the Listening to People Process and Duty of Candour procedure. In cases where a nominated representative is acting on behalf of a service user with capacity, consent for the representative to act will need to be obtained from the service user in the first instance and will be kept under review throughout the process.

In situations where a person is acting on behalf of an individual who indicate that they do not wish to engage or communicate with the Trust, the individual's wishes should be respected. However, the incident may continue to be investigated to ensure that there is no prospect of harm arising to other individuals and that lessons can be learned with quality improvements made.

Where the individual has died, either before or during the investigation, consent must be obtained from the legal representative acting on behalf of the individual's estate, together with evidence. It is important to know that a next of kin themselves do not automatically have legal authority. The Explanatory Leaflet Next of Kin clarifies that only certain legally appointed individuals can act following the death of an individual and what documents are required to prove the validity of the legal representative.

When mental capacity is in doubt, only a representative with a valid Lasting Power of Attorney (LPA) for Health and Welfare can legally make decisions about a person’s care or treatment. A financial LPA cannot be used for health-related decisions and is therefore not accepted in these circumstances. The representative must provide proof of the correct LPA before acting. Without this legal authority a representative is unable to make decisions on behalf of someone who lacks mental capacity.

7.6 Serious Case Reviews

In the event of adverse outcomes that affect large numbers of service users, a serious case review may be required to be undertaken retrospectively or, following a decision made by the Medical Examiner Service or coroner, as part of an inquest, where the cause of death was not known at the time of the incident. The Trust will ensure that the Listening to People Process, the Duty of Candour procedures and Coroner's requests, are followed for all affected individuals.

7.7 Incidents occurring before 1st April 2023

The Duty of Candour is not intended to operate in respect of adverse outcomes which occurred before the 1st of April 2023.

8.0 The Listening to People Process

The Listening to People Process promotes a cultural shift towards placing the individual's experience and voice at the heart of decision making and service improvement, underpinned by four core principles: -

- The Listening to People process mandates that complainants are actively listened to and treated with empathy and respect; that concerns are investigated proportionally and effectively; that NHS organisations learn from complaints and incidents to reduce future recurrence and that leaders provide assurance that meets regulatory requirements.

- As part of the Listening to People process, it is a requirement to use plain language and clear, compassionate communication throughout, with complex legal or medical terminology properly explained.

- There is a requirement for a mandatory offer of listening discussions: where NHS organisations take on board the experiences of individuals raising concerns. Examples can include a "listening discussion" (via telephone, video, or in-person (face-to-face) meeting) ensuring the complainant feels heard and understood and that they are actively offered access to advocacy, bereavement (if required) and legal support and that new timescales are observed and followed with mandatory checks in place for an effective resolution. Where a formal investigation is required, there is a requirement to explain the Redress arrangements and what is meant by a qualifying liability.

- There is also the requirement to clarify the nature of the concerns and identifying the required/desired outcome to achieve a satisfactory resolution and also undertake an assessment as to whether the concern can proceed under Stage 1 or Stage 2 of the Listening to People Process.

- It is a requirement that Datix Cymru is updated with the relevant rationale and decision making of the outcome that has been achieved, and that all appropriate fields have been completed before closure of the record is affected.

8.1 Complaints that occurred before 1st April 2026

The Listening to People Process, implemented on 1st April 2026 in accordance with the NHS (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011, as amended in October 2025, is not retrospective. Any concern raised prior to this date will be investigated in accordance with the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 (as amended 2023).

8.2 When more than one NHS organisation is involved in a concern

In situations where the Trust is part of an episode of care/concern with other NHS organisation(s), the Trust will fulfil its responsibilities in line with the Listening to People Process and Duty of Candour procedures (Wales) (2023). Any additional NHS body involved in the care/treatment of an individual will be required to be notified within 2 working

days of the Trust becoming aware of the concern and the involvement of another NHS organisation.

8.3 Initial Assessment and Grading, including Financial Threshold

At the point a concern is first received, the Trust will undertake an initial assessment to determine the nature, seriousness, and most appropriate route for management. This early grading process ensures that concerns are handled in a proportionate, efficient, and effective manner, in line with the Listening to People Process, the Duty of Candour Procedure, the Regulations, and local procedures. The assessment will consider the type and complexity of the issues raised, whether the matter can be resolved quickly through Early Resolution, or whether it requires a formal Stage 2 investigation. It will also take into account any indication of actual or potential harm, patient safety risks, or safeguarding concerns that may require immediate escalation.

As part of this assessment, the Trust will consider the likely financial value of any potential claim to determine whether the concern may exceed the £50,000 financial threshold. This ensures that no admission of qualifying liability is made where potential damages could surpass this limit. Although estimating quantum at an early stage can be challenging, the Trust will draw on available indicators such as the Judicial College Guidelines, Lawtel case summaries, relevant legislation, and current legal developments. The assessment will also establish whether the concern meets the threshold for the Duty of Candour, including whether moderate or above harm has occurred and whether a formal notification and apology are required.

In addition, the Trust will confirm whether the person raising the concern is the service user or acting on their behalf, and whether explicit consent is required to proceed, particularly where access to medical records is necessary. Consideration will also be given to any vulnerability, communication needs, or reasonable adjustments required, including advocacy or support linked to protected characteristics. Following this assessment, the Trust will determine whether the concern is suitable for Early Resolution within ten working days of acknowledgement or whether it should progress to a Stage 2 investigation, with escalation to specialist teams where appropriate.

8.4 Acknowledging concerns

Acknowledgement of a concern must be issued within five working days of receipt of the concern. The following requirements apply: -

- Acknowledging the concern within the required timescale according to the Regulations;
- Obtaining consent;
- Providing a point of contact with contact details;
- Offering a Listening Discussion within the required timeframe;
- Undertaking an assessment of the issues raised;
- Providing an apology;
- Offering empathy and understanding;

- Providing an offer of advocacy, legal and support services, including bereavement services, as appropriate;
- Offering provision of accessibility adjustments where required;
- Providing an opportunity for concerns to be raised in the Welsh Language and making provision for any community language, as required, including providing Easy Read leaflets in the language of an individual's choice;
- Clarifying desired outcome and expectation;
- Explaining the difference between the routes available under the Listening to People Process i.e. stage 1 and stage 2;
- Responding within the timescales outlined in the Listening to People Process.

8.5 Listening Discussion

- In accordance with the Listening to People Process, the Trust will offer a Listening Discussion within the required timescales. This may be provided at the same time as the acknowledgement, where action may be possible to be taken promptly. The Listening Discussion must take place not later than 5 working days after the concern has been acknowledged.
- The Listening Discussion may take place by telephone, video call, or face-to-face, and must be led by a trained member of staff with strong active-listening abilities, compassion, inquiry skills, and sufficient authority to act. The offer of a discussion should also include any necessary support, such as advocacy, interpreter services, reasonable adjustments, or involvement of Llais, with arrangements made in advance to ensure the person is properly supported.
- During the Listening Discussion, the staff member must allow uninterrupted narrative, seek clarity on key points, and keep an accurate and proportionate record. The discussion should cover the nature and impact of the concern, the outcomes the person is seeking, and the available options for resolution.
- Explicit consent must be obtained.
- If Stage 2 is considered the most appropriate route following assessment of the issues raised, the staff member must explain how the investigation will be conducted, obtain consent to access and review medical records, signpost advocacy and support, and agree a timeframe for a proportionate investigation.
- In addition, where Stage 2 is indicated, the Redress arrangements must also be explained, including what is meant by a qualifying liability (QL).
- The Trust will then undertake an appropriate and proportionate investigation, complete the outcomes in writing with a final response within the required timescales, provide a copy of the record where a verbal complaint was received under Stage 1, and issue the Listening to People leaflet.
- If the person declines the Listening Discussion, the Trust will write to the individual outlining the available options and inviting the individual to consider and decide the matters covered by Regulation 22(4) of the Regulations.

8.6 Early Resolution Concerns

The Trust will manage Stage 1 (Early Resolution) concerns in line with the Listening to People Process, ensuring resolution is achieved to the satisfaction of the complainant within 10 working days from the date of acknowledgement and ensure that the concern is graded appropriately.

As indicated above, the Trust is to ensure that a Listening Discussion takes place within the required timeframe i.e. within 5 working days of acknowledgement of the concern, allowing the individual to articulate the concerns, clarify what actions will be taken, together with the Trust's offer of a sincere apology and reaching a desired outcome within the 10 working days from the date the concern was acknowledged. Regulation 14 (5) expressly provides that a concern which is resolved during the early resolution stage is excluded from the scope of the investigation and redress arrangements under regulations 23 to 48. This does not exclude concerns where harm is alleged or maybe present. Following a satisfactory outcome, the Trust will issue a written response within 10 working days and will provide a copy of the record where a verbal complaint was raised.
If, however, following this time, the concern remains unresolved, the concern(s) will be managed in line with Listening to People Process as a Stage 2 (Investigation) concern or with the agreement of the individual raising a concern, that the matter is capable of being resolved under Stage 1.

8.7 Stage 2 – Formal Investigation and Timescales

Where it is indicated that a more in-depth investigation is required to reach a conclusion, or it has not been possible to find a resolution to Stage 1 within the 10 working days (unless it is agreed with the complainant that the matter is to remain with Early Resolution and it is capable of being resolved under Stage 1), the Trust will provide an appropriate timescale for a proportionate investigation to be undertaken. The timescales vary depending on the nature of the concerns, however, the Listening to People Process provides 30, 60, 90 or 120 working days in which to undertake a formal investigation and provide a final response.

The Trust will provide a full and comprehensive response/interim report usually within 30 working days from the date the concern is received. If the Trust is unable to comply with this timeframe, the Trust will ensure that it provides a timeframe for the handling of the investigation i.e. 60/90/120 working days. If no timeframe is provided, the concern will automatically default to 30 working days. If it anticipated that a delay would occur, there is a requirement to:

(a) notify the person raising the complaint or the person affected by the incident, outlining the reason for the delay, and advising when the response will be available; and
(b) send the comprehensive/final response as soon as reasonably practicable and within 120 working days.

8.8 Concerns Notified by a Third Party

The Trust will ensure that concerns notified by a third party acting as a representative on behalf of another are handled in line with the Listening to People process, ensuring a best interest assessment is completed and proportionate response considered.

8.9 Concerns Received from Members of the Senedd/Members of Parliament

The Trust will ensure that concerns received from the Welsh Government, Members of the Senedd, Members of Parliament, or other elected member on behalf of a constituent, are dealt with as soon as possible and a response provided at the earliest opportunity. For the sharing of personal data, the Trust will adhere to the requirements of The Data Protection (Processing of Sensitive Personal Data) (Elected Representatives) Order (2002).

8.10 Concerns Relating to Children and Young People.

Where a concern is notified by a child or young person, the Trust will ensure it meets its support, assistance, and advocacy responsibilities in line with the Welsh Government's Model for Delivering Advocacy Services to Children and Young People in Wales. When a concern is raised on behalf of a child or young person, the Trust will establish whether the child or young person wishes to raise the concern themselves or is content for the individual who notified the concern to act on their behalf. If the child or young person does not wish the concern to be investigated, the Trust will assess the circumstances and, where appropriate, seek specialist advice to support decision-making. In any situation where safeguarding issues are identified, the Trust will invoke the All-Wales Safeguarding Procedures.

8.11 Concerns Raised by Prisoners

The Trust will handle and investigate concerns raised by prisoners in the same manner as all other concerns, in accordance with the Listening to People Process. All concerns will be managed in a fair, equitable, and non-discriminatory manner. Prisoners will be offered, and have the right to access, advocacy services provided by Llais, Social Care, or Mental Health Services, as appropriate to their individual needs.

8.12 Concerns raised by individuals Lacking Capacity or Vulnerable Adults

The Trust will ensure that all concerns raised by individuals lacking capacity or vulnerable adults are handled in an equitable and accessible manner with reasonable adjustments and enhanced support and advocacy services provided, as required.

In circumstances where concerns regarding mental capacity are raised, the Trust will ensure all assessments align with the requirements of the Mental Capacity Act (2005). During this process, if any safeguarding and public protection issues are identified the Trust will invoke the All-Wales Safeguarding Procedures.

8.13 Concerns raised through Advocacy Services

The Trust will work in collaboration with advocacy services and ensure that concerns raised on behalf of service users are managed in line with the Listening to People Process.

8.14 Concerns from Solicitors / Intention to Litigate / Requests for Compensation

The Trust will ensure that concerns, litigation intents and compensation requests are managed by the Corporate Quality and Safety Team in accordance with the governance and framework of the Listening to People process, with exception of a concern in respect of which court proceedings have already been issued, including the pre-action stage of those proceedings, which should not be further investigated.

8.15 Concerns relating to people with a Disability

In accordance with the Equality Act 2010, the Trust will make reasonable adjustments to ensure that the concerns process is fully accessible and that appropriate support is provided for service users with a disability and protected characteristics. The Trust is committed to delivering a fair, equitable, and non-discriminatory service, ensuring that no individual is disadvantaged or treated less favourably on the basis of any protected characteristic, including age, disability, gender reassignment, marriage or civil partnership, pregnancy or maternity, race, religion or belief, sex, or sexual orientation.

8.16 Concerns relating to British Sign Language (BSL)

The Trust recognises British Sign Language (BSL) as a recognised language and will ensure that the concerns process is fully accessible to service users who communicate through BSL through the provision of appropriate services. The Trust is committed to delivering a fair, equitable, and non-discriminatory service, and will make reasonable adjustments as required to support individuals' communication needs.

8.17 Concerns relating to Blind and Partially Sighted Individuals

The Trust will ensure that alternative methods of communication are available to support individuals who are blind or partially sighted, including access to Braille and large-print versions of information, so that they are fully enabled to raise concerns. This commitment forms part of the Trust's wider approach to providing an accessible, fair, and non-discriminatory concerns process for all service users.

8.18 Concerns involving Contracted Services

The Trust will ensure that all contracted services are aware of this policy, understand its practical application, and recognise their roles and responsibilities in the management of concerns. All contracted providers are expected to adhere fully to the requirements of the Regulations and to apply the Listening to People Process consistently and appropriately.

9. Welsh Language

When dealing with concerns, the Trust will take account of its statutory duties in relation to the provision of services in Welsh and will ensure compliance with the duties set under the Welsh Language (Wales) Measure (2011) and Welsh Language Standards. All concerns received in Welsh will be responded to in Welsh in accordance with the Listening to People Process. The Trust will ensure:

- All written communication is provided in Welsh.
- Welsh interpretation for telephone or face-to-face meetings.
- Provision of bilingual information resources.
- Adopt a proactive approach to language choice and need in Wales.
- Ensure Welsh Language Needs are met.

10. Raising Concerns

In line with the Regulations, the Trust has a single point of contact for raising a concern:

Executive Director of Nursing Allied Health Professionals (AHP) & Health Science
Velindre Trust Head Quarters
2 Charnwood Court
Heol Billingsley
Parc Nantgarw
Cardiff
CF15 7QZ

Email: handlingconcernsvelindre@wales.nhs.uk

Telephone: 02920 196191

11. Concerns received from Medical Examiners

The Trust will ensure robust corporate procedures are in place to receive and respond to concerns received from the Medical Examiner's office and will comply with any requests from the Medical Examiner's office, as required.

12. Concerns Referred to Coroners Inquests

The Trust will ensure that robust procedures are in place to investigate concerns referred to HM Coroners in line with the Regulations. For further information please see the Inquests Guidance.

12.1 Bereavement

The Trust recognises that those who have raised concerns following the loss of a loved one and are experiencing grief may find it more difficult to engage with the concerns handling processes. It is important that staff treat individuals with sensitivity, dignity and compassion throughout and take time to understand the individual's emotional state. This might include, for example, avoiding placing unnecessary pressure on individuals suffering grief, and offering flexibility around meetings, information-sharing and timeframes wherever possible.

Individuals who have raised concerns in relation to the death of a service user, should be offered assistance and signposted to appropriate bereavement and emotional-support services, when required. Staff must be mindful that concerns are managed in a way that is supportive, respectful and mindful of the impact of grief.

A number of organisations and charities offer support and assistance. Links to charitable organisations are found in the updated Redress leaflet.

The National Bereavement Alliance is a UK coalition of charities, professional bodies and support organisations working together to improve the quality, consistency and accessibility of bereavement support. It provides a collective voice for NHS workers, promotes best practice, influences national policy and helps ensure that people who are grieving can access appropriate, compassionate support when they need it. The link can be accessed here https://nationalbereavementalliance.org.uk/

13. Consent to Investigate Concerns

The Trust will ensure that the consent policy is followed, and service user consent obtained for all concern investigations that require access to medical records, if the patient/donor does not provide consent to access their clinical/donor record the Trust will take a view on whether an investigation without access to the medical records will be possible.

14. Consent Involving Other Organisations

Where the Trust is notified of a concern that involves the functions of more than one responsible body, it will first seek the consent of the complainant. Within 2 days, the Trust will contact all relevant organisations, and the lead organisation will be identified in discussions with the complainant and involved organisations.

15. Time limits for notification of a Concern

The Trust aligns the time limits for notification of a concern with the Listening to People Process and the Regulations. This requires concerns to be notified no later than 12 months from the date on which the concern occurred, or if later, 12 months from the date the person raising the concern realised they had a concern. Concerns received after these timescales will be considered by the Trust to determine the reason for the delay in reporting and the possibility of investigation being thorough and fair due to the time lapse. A concern must not be investigated more than three years from the date of knowledge or from the date when the service user became aware that a concern existed. This is aligned with the Civil Procedural Rules in accordance with the Limitation Act 1980.

16. Withdrawal of Concerns

The Trust acknowledges that a concern can be withdrawn at any time by the complainant. Such withdrawal requests can be provided in writing or verbally and will be acknowledged in writing by the Trust. Despite this withdrawal, the Trust may continue with their investigation in the interests of justice to consider the findings and, where learning is identified, to put in place remedial action to prevent similar concerns from being raised in the future.

If, following every reasonable effort to contact the person notifying the concern, the Trust is unable to reach the individual, this will be treated as a withdrawal of the concern as above.

17. Nationally Reportable Incidents

The Trust will comply with the National Reportable Incidents Policy in relation to the management of concerns.

The Trust will ensure a concern raised by a complainant that has already been reported and investigated and commenced as a nationally reportable incident, will be managed in accordance with the Regulations, with the investigation progressing in line with the National Reportable Incidents Policy and Listening to People Process, ensuring the person raising the concern is kept informed of investigations and outcomes.

Where a concern is received, and it becomes apparent that there has been a serious incident that the Trust was previously unaware of, the Trust will ensure the incident is reported within Datix Cymru system and the National Reportable Incident process followed, providing an explanation in Datix Cymru of the reasons why the 30 working day time frame has not been met and the likelihood of when a response will be expected.

18. Final Response issued under Regulation 24

The Trust will ensure that requirements of the Listening to People Process and associated investigations and reporting requirements are met. Where the Trust determines that a concern does not give rise to a breach of duty or a breach of duty has been identified that has not caused harm, the Trust will issue a final response under Regulation 24.

The response must clearly explain the investigation and its findings, outlining the evidence considered, and provide a transparent account of how the conclusion was reached. It should also reassure the individual that their concern has been fully reviewed in accordance with the Regulations and the Listening to People Process.

The Regulation 24 response must be provided in writing and include information on the individual's right to pursue the matter through alternative routes if they remain dissatisfied, for example, via the Public Service Ombudsman of Wales. The Trust must ensure that the communication is clear, compassionate, and accessible and written in a manner that enables the person to understand the outcome.

19. Dissatisfaction Expressed following a final response

In the event additional concerns or new concerns are raised from an individual that were not previously investigated following the issue of a final response, the Trust will ensure the concern is reopened, investigated, and acknowledged in the usual manner. However, if a complainant is dissatisfied with their response and there are no new issues to investigate, the Trust will manage the concern in accordance with the Listening to People Process and will direct the individual to the Public Services Ombudsman of Wales. The Public Service Ombudsman for Wales is independent of all government bodies and will look into complaints raised by individuals in relation to NHS healthcare matters.

20. Interim Report (Regulation 26) – When a Breach of Duty is identified, and harm has occurred, or likely to have occurred, resulting in a possible qualifying liability

The Trust will ensure compliance with the Listening to People Process.

In cases where the Trust considers that, following investigation, both a breach of duty has been identified which has caused potential harm, or actual harm, an interim report and response under Regulation 26 of the Listening to People Process will be issued following receipt of when the concern was received and within the required timeframe agreed for a response to be issued i.e. within 30 working days or where the Duty of Candour is triggered, the day upon which the "in person" notification under Regulation 4(1) of the Duty of Candour Regulations was given.

The Trust will ensure that in cases where a breach of duty is considered to have caused harm, the investigative findings will be considered by the Trust's Breach of Duty Panel, who will make a decision in relation to whether a confirmed breach of duty has occurred that has potentially caused harm or harm.

The Regulation 26 response must include:-

- A summary of the nature and substance of the issues contained in the concern.
- A description of the investigation undertaken to date.
- A description of why, in the opinion of the Trust, there is or may be a qualifying liability.
- A copy of any relevant medical records.
- An explanation of how to access legal advice without charge.
- An explanation of advocacy and support services which may be of assistance.
- An explanation of the process for considering a qualifying liability
- Confirmation that the full investigation report will be made available to the person seeking Redress.
- An offer of an opportunity to discuss the contents of the interim report with the individual involved.
- The interim report is required to receive final approval and sign off by the Executive Director Nursing, AHP's and Health Science before issuing it to the individual concerned.

If it is not possible to issue a Regulation 26 interim response within the required timeframe, the Trust will ensure the person raising the concern will be informed of the reason for the delay and a timeframe of when the response can be expected.

Once the interim response is issued, the Trust will ensure the matter is forwarded to the Trust Claims, Redress & Inquest Managers for further investigation under the Redress arrangements, as referenced within the Listening to People Process and Regulations. There is a requirement that a final response is due to be issued no later than 120 working days.

21 Post Closure contact - Public Service Ombudsman of Wales

The Trust will ensure compliance with the Public Services Ombudsman (Wales) Act (2019) and inform any individuals that are dissatisfied with the Trust final response of their right to contact the Public Service Ombudsman for Wales, who will review the matter on their behalf.

The Ombudsman's contact details are:
Phone: 0300 790 0203
E-mail: ask@ombudsman.wales
Website: www.ombudsman.wales
Address: Public Services Ombudsman for Wales
1 Ffordd yr Hen Gae
Pencoed
CF35 5LJ

21.1 Investigation by the Public Services Ombudsman of Wales (PSOW)

On receiving a complaint from the PSOW, the Trust will provide an acknowledgement of receipt to the PSOW within 5 working days and will investigate and respond to the PSOW within 20 days. If, for any reason, the required timescales are difficult to achieve the Trust will request an extension from PSOW.

In response to conclusions received from the PSOW, the Trust will ensure that identified opportunities for learning and improvement are actioned and shared, including the making of any redress consideration recommended by the PSOW.

22. Redress

The Trust will ensure compliance with the Redress requirements of the Regulations and Listening to People Process, including.

- The making of an offer of compensation in satisfaction of any right to bring civil proceedings in respect of a qualifying liability.
- The giving of an explanation.
- The making of a formal apology.
- The provision of a report on the action/s which has been, or will be, taken to prevent a similar occurrence from arising.
- The provision of any care/remedial treatment required.

Following an opinion, either from inhouse clinicians or an independent expert (on a joint basis with the individual of nominated representative concerned), the report findings are shared with the appropriate division and relevant staff members involved in the investigation, as required.

In circumstances when a person is seeking Redress, the Trust will ensure findings of the investigation are recorded in an investigation report in accordance with Regulation 31, with the report that contains:

- copies of any independent expert advice used to determine whether there is a liability.

- a statement by the Trust confirming whether there is a liability and
- the rationale for the Trust decision.

The Trust will ensure the report is provided in line with the Regulations to the person who raised the concern.

Where an investigation report cannot be provided within the set 120 working day timescale, the Trust will inform the person raising the concern of both the reason for the delay and expected date for response.

22.1 Regulation 33 Response

Following approval from the Redress Panel, the Trust will ensure compliance with Regulation 33. Where financial compensation is due, a Regulation 33 response will be prepared by the Trust Claims, Inquests and Redress Manager and will include an appropriate financial offer to settle the matter on a full and final basis. This response will include a waiver confirming that the individual agrees not to pursue a civil claim in relation to the concerns that formed the basis of the investigation.

Once the Regulation 33 response has been issued, the person raising the concern will have six months from the date of the response, or from the date the incident was identified, to accept the offer. If no response is received within this period, the concern will be closed within nine months.

Any financial offer made under the Listening to People Process must not exceed £50,000. Where the likely financial value of the matter is assessed as exceeding this threshold, the concern must be considered for removal from the Redress arrangements or advice sought from NHS Wales Shared Services Partnership (NWSSP) Legal & Risk Services, if required.

In such cases, the individual will be advised to seek independent legal advice regarding the potential pursuit of a civil claim. No admission of qualifying liability will be made, and the matter will be removed from the Listening to People Process.

Where no harm has been found that would amount to a loss and/or financial compensation, a final response will be issued in accordance with the regulatory requirements within the required timeframe. This response must be issued no later than 120 working days. The response must provide an outline of the key aspects investigated, the learning that has or will be actioned, and the reason and rationale for the decision made.

22.2 Compensation Recovery Unit (CRU) Certificate

The Trust Claims, Inquests and Redress Manager is responsible for requesting, or ensuring that a Compensation Recovery Unit (CRU) certificate is obtained from the Department for Work and Pensions where an investigation establishes that harm may have occurred. This requirement forms part of the Trust’s statutory obligations.

Where harm is confirmed and NHS charges or recoverable benefits apply, the Trust Claims, Inquests and Redress Manager will arrange for the appropriate payment and discharge of

the CRU certificate. In circumstances where the NHS charges or CRU liability exceeds £3,000, the matter will be referred to NWSSP Legal and Risk Services for advice, in accordance with Welsh Risk Pool guidance.

23. Behaviour, Conduct and Unreasonable Demands during a Concerns Investigation

The Trust will ensure that people raising concerns are heard, understood, and respected. On occasions there may be times when persons raising the concern acts out of character and become determined, forceful, angry and make unreasonable demands of staff. In such circumstances, the Trust has a zero-tolerance policy on unreasonable, unacceptable abusive or aggressive, or violent behaviour.

For the purpose of this policy, unreasonable, unacceptable, abusive, or aggressive, or violent behaviour is considered as:

- Behaviour that produces damaging or harmful effects, physically or emotionally on other people.
- Persistent unacceptable behaviour is demonstrated on several occasions within a given period of time.

Examples of unacceptable, aggressive or abusive behaviour recognised by the Trust include:

- Verbal threats, unsubstantiated allegations or offensive statements can also be termed as abusive violent behaviour.
- Threatening remarks e.g., both written and oral.
- Demands for responses within unrealistic timescales, repeatedly phoning, writing, or insisting on speaking to a particular member of staff.

The Trust will follow its Violence and Aggression Policy to ensure that staff are protected and action taken if required.

24. Monitoring Arrangements

The Trust will ensure a record is held of the following matters:

- Each concern notified.
- The outcome of each concern.
- The time taken to investigate the concern.
- The reasons where any investigation exceeded the time period.

The Trust will ensure that this information, and comprehensive analysis of concerns activity and learning will be reported to the Executive Management Board and Trust Quality and Safety Performance Committee on a quarterly basis.

The Trust Integrated Quality &Safety Group will provide oversight for the quarterly reports and will ensure the triangulation and robust analysis of data.

The Trust will prepare and publish an annual Integrated Quality and Safety/Listening to People report by the 31st of October every year, regarding the delivery of the Regulations and application of the Duty of Candour in line with the requirements of the Regulations, Duty of Candour, and Listening to People Process. This report will be clearly displayed on the Trust's internet site.

25. Learning from Concerns

The Trust will ensure that arrangements are in place to review and assess the outcome of any concern that has been subject to investigation under the Listening to People Process.

The Trust will ensure that any deficiencies in its actions or in the provision of its services identified during the investigation are recognised, acknowledged, owned, and acted upon. Where improvement requires embedding, an improvement plan will be developed and monitored through the Trust's AMAT system.

The improvement plan will identify learning for wider sharing across the Trust and will be disseminated as appropriate, including through mechanisms that enable learning to be shared across the wider NHS sector where suitable. It will be reviewed and reported on regularly within service divisions and at Trust-wide level to ensure that actions are implemented and improvements achieved, reducing the risk of recurrence. The Trust will also ensure that learning is used to target problem areas and to consider opportunities to strengthen policies, procedures, and services.

25.1 Learning from Events Reports (LFERs)

The Trust will ensure that Learning from Events Reports are completed following the investigation of concerns where learning, improvement, or system change has been identified following the establishment of a qualifying liability. The Claims, Redress and Inquests Manager will prepare the Learning from Events Report which will then be actioned by the relevant division within the required timeframe.

These reports provide a structured summary of the issues identified, the actions taken, and the improvements made to prevent recurrence. Timescales are strict for the submission of a Learning from Events Report. These are required to be issued to the Welsh Risk Pool no later than 4 months from the date when a qualifying liability response was issued.

The Learning from Events Report support organisational learning by capturing key themes, highlighting contributory factors, and identifying opportunities to strengthen practice, processes, and service delivery. Learning from Events Reports will be shared through appropriate governance structures, enabling oversight, dissemination of learning, and assurance that improvements are embedded across the Trust and, where appropriate, shared more widely across the NHS.

26. Supporting Staff

26.1 Staff involved in Concerns

The Trust recognises that staff involved in concerns can be affected emotionally and psychologically. The Trust will therefore ensure that all staff are provided with a psychologically safe environment for all those involved in the concerns investigations through:

- Actively promoting an open and fair culture that fosters peer support and discourages the attribution of blame following the Speaking up Safely framework and procedure.
- That Velindre University NHS Trust will work towards a culture where human error is understood to be a consequence of flaws in the systems, not necessarily caused by the individual.
- Provide ongoing support via Line Managers, Clinical Supervisors, Workforce department, Occupational health colleagues and Trade Union representatives.
- Ensuring the provision of mentorship and coaching, as required.
- Signpost staff to their Employee Wellbeing Service/Occupational Health/Employee Assistance Programmes and psychology services.
- Provide and maintain up-to-date information on the support systems currently available for staff, including counselling services offered by professional bodies.

26.2 Concerns Containing Allegations against Staff

Where concerns raised contain allegations against a staff member(s), the Trust will ensure relevant staff member/s receive a copy of the key issues identified at the beginning of the investigation and will be provided support as required throughout the process.

26.3 Concerns and Disciplinary Procedure

Any disciplinary proceedings arising from issues identified during the management or investigation of a concern will be handled in accordance with the Trust's Disciplinary Policy. The Listening to People Process is not a mechanism for determining disciplinary action; however, where an investigation highlights potential misconduct, unsafe practice, or behaviour that may warrant formal consideration, the matter will be referred to the appropriate senior manager or People and Organisational Development representative.

The decision to initiate disciplinary action will be made independently of the concerns process and will follow the principles of fairness, proportionality, confidentiality, and compliance with employment legislation. Staff involved will be supported appropriately, and the separation between organisational learning and individual performance management will be maintained. While the primary aim of the Listening to People Process is improvement, the Trust has a duty to act where concerns indicate that staff conduct, capability, or professional practice may require formal review.

27. Equality Impact Assessment

This policy has been screened for relevance to equality, and no potential negative impact has been identified. The Trust recognises, however, that some members of the community who may wish to raise a concern might not feel able to do so. This may arise from cultural, social, gender-related, or other factors, including disability or sensory loss, any of which may create

barriers to effective communication. Staff are required to remain mindful of the issues that may prevent individuals from raising a concern and to take proactive steps to reassure people that it is safe and acceptable for them to do so.

The Trust is committed to ensuring that all individuals are aware of, and able to benefit from, the protections afforded under the Listening to People Process. These protections include the right to raise a concern without fear of disadvantage, discrimination, or negative consequences, and the assurance that concerns will be handled fairly, sensitively, and without bias. The Trust will continue to develop its understanding of the barriers that may prevent people from speaking up and will work to remove these barriers, ensuring that everyone has equitable access to the concerns process and feels confident and supported in raising issues about their care or experience.

28. Policy Compliance

The Trust and its divisions will ensure full adherence to this policy and will provide role-specific concerns-handling and Duty of Candour training to equip staff with the knowledge and skills required to fulfil their responsibilities effectively. This includes ensuring that staff understand their obligations under the Listening to People Process and the Duty of Candour Procedure, and that they are confident in applying these requirements in practice. Training will support staff to recognise concerns, respond appropriately, communicate sensitively, and uphold the protections afforded to individuals raising concerns. Ongoing compliance will be monitored through established governance arrangements to ensure that standards are maintained and that the Trust continues to meet its statutory duties.

29. Information Governance

The Duty of Confidentiality is an important aspect in relation to concerns handling. All Trust staff are required to maintain confidentiality and are required to protect personal data as outlined by legislation, including the Common Law Duty of Confidentiality and the Data Protection Act 2018, which includes the retained EU General Data Protection Regulation GDPR 679/2016 (known as UK GDPR). UK GDPR sets out the key data protection principles, rights of individuals (known as Data Subjects), and obligations for processing personal information.

The Trust acts as the “Data Controller” in respect of personal data, as defined in Article 4 UK GDPR. Staff responsible for processing personal data are to follow the 'seven data protection principles' which are contained in Article 5 UK GDPR. This means that whenever staff process personal data, they must do so; lawfully, fairly and transparently and that the process is for specific, explicit and legitimate purposes;

Staff are required to ensure that in relation to the purposes of processing, the data is adequate, relevant and limited for that purpose;

In addition, staff must ensure that the data processed is accurate, kept up-to-date and stored in a format which permits the data subject to be identified and kept for no longer than is absolutely necessary. Staff must also ensure that when the data is processed, appropriate

technical and organisational measures are in place to protect the integrity and confidentiality of the data.

The final data protection principle is accountability; All Staff are accountable for the data that they process. The obligation to comply with the Data Protection Principles sits alongside the eight Caldicott principles, Section 8 of the Human Rights Act 1998, Section 40 of the Freedom of Information Act 2000, and Section 13 of the Environmental Information Regulations 2004.

Information in relation to complaints should not be disclosed/copied/ shown to any external agency without the permission of the Responsible Officer or nominated deputies on a "need to know basis."

All requests for access to such information should be directed in the first instance to the appropriate manager or nominated deputy or service lead for the subject of the concern.

The Trust has adopted the NHS Wales Records Management Code of Practice Health and Social Care 2022, in addition to supporting the development of the Wales Accord on the Sharing of Personal Information (WASPI) as a legally binding framework.

All staff are bound by their contractual duty of confidentiality regardless of their role and status and are required to respect the personal data and privacy of others. All staff must not access information about any individual who they are not providing care or treatment for, or in relation to the administration of services, unless in a professional capacity. They are not permitted to access their own data. Any request for their own personal data must be made as a Subject Access Request. The Trust Head of Information Governance can provide further information and advice if required in relation to access rights and the lawful sharing of personal data.

The Information Commissioner's Office (ICO) has detailed guidance on data sharing on its website and has issued a data sharing code of practice, the Code of Practice can be accessed https://ico.org.uk/for-organisations/guide-to-data-protection/ico-codes-of-practice/datahttps://ico.org.uk/for-organisations/guide-to-data-protection/ico-codes-of-practice/data-sharing-a-code-of-practice/sharing-a-code-of-practice/

It must be noted that the threshold for reporting a data breach to the Information Commissioner is much higher than that contained within the Duty of Candour. This is outlined in Article 33(1) UK GDPR, which states:

"In the case of a personal data breach, the controller shall, without undue delay and, where feasible, not later than 72 hours after having become aware of it, notify the personal data breach to the Commissioner, unless the personal data breach is unlikely to result in a risk to the rights and freedoms of natural persons. Where the notification under this paragraph is not made within 72 hours, it shall be accompanied by reasons for the delay".

The Trust's Head of Information Governance must be contacted where a data breach has occurred so that an assessment of risk to the rights and freedoms of the natural person (data subject) can be made. This is to ensure alignment between the Listening to People Process, Duty of Candour and Data Protection legislation requirements.

Advice and guidance in relation to any aspect of Information Governance considerations can be obtained from the Trusts Head of Information Governance.

VelindreInformationGovernance@wales.nhs.uk

30. Managing Media Interest / Media Communications

The management of media interest relating to incidents, whether individually or collectively, will be coordinated by the Corporate Department in conjunction with the Trust's People and OD Department and Communications Department, as required.

All requests for assistance or comment must be directed to the Corporate Department, who will provide appropriate advice and support.

No statements, comments, or information are to be issued to the media or press without prior consultation with, and approval from, the Trust's relevant department. This ensures that all external communications are accurate, consistent, and aligned with the Trust's governance and legal obligations.

31. References

This policy has been prepared with reference to the Listening to People Process, NHS (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 (amended 2025) together with the Duty of Candour Procedure and associated national guidance to ensure full regulatory compliance. In updating this policy, the Trust has considered the statutory requirements governing the management of concerns, the provision of redress, and the duties owed to individuals when harm may have occurred. The policy also reflects the principles and expectations set out in Welsh Government guidance, including the need for openness, transparency, and a consistent approach to learning from concerns. By grounding the policy in these regulatory frameworks, the Trust ensures that its processes align with national standards, support the fair and timely handling of concerns, and uphold the protections afforded to individuals under the Listening to People Process. The following legislative and statutory guidance have been considered: -

- The Health and Social Care (Quality and Engagement) (Wales) (2020) (Duty of Quality and Duty of Candour)
- The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) (Amendment) Regulations 2025 ('the Regulations)
- The Listening to People Process: NHS Wales Complaints, Incidents and Redress process
- Public Service Ombudsman for Wales Act (2019)
- Duty of Candour Procedure (Wales) (2023)
- The Equality Act 2010 and Public Sector Equality Duty
- The Mental Health Act (as amended in 2025)
- NHS Wales National Policy on Patient Safety Incident Reporting & Management (2023)
- Limitation Act 1980 and Civil Procedural Rules
- People's Pledge/Citizen's Voice
- General Data Protection Regulations and Confidentiality
- The Welsh Risk Pool Procedures