

**CWM TAF MORGANNWG (CTM)
Concerns
Policy & Procedures**

Policy Details:

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Target Audience:

People who need to know this document in detail	All Health Board Staff dealing with Concerns
People who need to have a broad understanding of this document	Board Members
People who need to know that this document exists	All Health Board Staff

Integrated Impact Assessment:

Equality Impact Assessment Date & Outcome	Date: N/A Approved
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Aligns to the following Wellbeing of Future Generation Act Objective	Provide high quality, evidenced based, and accessible care

Where	When	Why
Quality and Safety Committee	01.02.24	

Detail of change	Why change made?	Page number	Date of change	Version	Name of Policy Author
Inclusion of Duty of Candour requirements	Duty of Candour implementation 2023	21	01.02.24		
Change from Locality to Care Group	Should reflect new operating model	Through out	01.02.24		
Reference to Serious Incident replaced by Nationally Reportable Incident	Should reflect changes to National Incident Reporting Framework introduced on 14.06.2021	26	01.02.24		
Amendment to timescale in which to acknowledge complaints within 5 working days	To reflect updates to Putting Things Right Guidance	17	01.02.24		
Reference to the Community Health Council being replaced by Llais	To reflect the change in advocacy services offered	1	01.02.24		

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1. Purpose

The purpose of this policy is to support the effective management of complaints, patient safety incidents and redress. It is supported by the Health Board's incident reporting policy and procedure and should be read in conjunction with the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 and Putting Things Right Guidance (2013).

The policy, accompanying Standard Operating Procedures and the Incident Management Framework, detail the Health Board's arrangements and applies to:

- a. Complaints
- b. Patient safety incidents
- c. Redress
- d. Duty of Candour

Arrangements for dealing with concerns will be available in a variety of media, formats and languages and will include the internet and via posters and leaflets in public areas.

2. Policy Aim

The aim of this Policy reflects the purpose of the Putting Things Right legislation and guidance:

- Develop a culture of accepting and supporting when dealing with concerns about treatment and care, with staff at all levels being encouraged to apologise for adverse outcomes and to offer explanations why they may have arisen.
- Ensure a patient/user focus rather than process-driven, approach is evident throughout the organisation, which also empowers people to raise concerns and have them dealt with as soon as they arise.
- Emphasise the importance of resolving concerns in a timely fashion, openly and honestly – a philosophy of “investigate once, investigate well”.
- Ensure staff can be confident that investigations will be fair and impartial and that they will be supported throughout the process.
- Ensure learning from concerns and errors drives quality improvement and reduces adverse events, and avoidable harm to patients/users.
- Allow for redress to be provided in circumstances where there is a qualifying liability in tort in relation to the provisions of qualifying services. Redress may encompass apologies, explanations, action plans, remedial treatment and, if appropriate financial compensation.

3. Policy Scope

- a. This policy applies to all staff, permanent and temporary, employed by or working within the Health Board, including independent providers who have responsibility to report, manage and or be involved in concerns raised.

- b. The Policy covers concerns about:
 - Services, care & treatment provided by the Health Board;
 - Services, care & treatment provided by Health Board staff;
 - Services, care & treatment provided by independent contractors;
 - Services, care & treatment provided by the independent or voluntary sector which are funded by the Health Board;
 - Independent contractors are required to have a concerns procedure in place for their NHS patients that is in line with the regulations;
 - This policy does not apply to clinical services provided privately, even when provided within Health Board premises.

4. Policy Framework

This addresses the management of concerns and redress and sets out the principles for the handling of the investigations. It is supported by action cards, and should be read in conjunction with:

1. National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011.
2. Putting Things Right Guidance on Dealing with Concerns about the NHS from 1st April 2013.
3. Incident Management Framework.
4. Concerns SharePoint pages.
5. Being Open Policy.
6. Quality & Safety Framework.
7. Duty of Candour regulations

5. Roles and Responsibilities

The Regulations specifically require every NHS organisation to make it clear who is responsible, in their organisation, for the undertaking of the distinct roles and regulatory responsibilities as set out below:

a. Care Group/ Unit Clinical Directors, Nurse Directors, Service General Managers, are responsible for ensuring:

1. That a culture of openness is promoted and encouraged to ensure that staff report all concerns that are patient safety incidents and that concerns are robustly investigated in line with the Regulations and acted upon;
2. Effective and practical local arrangements are in place across all provided and commissioned services to ensure full implementation of and compliance with this policy and that these are communicated to staff;
3. That all staff receive patient safety/ concerns training and Datix Cymru training pertinent to their roles and responsibilities. Refresher training needs of staff must be determined at a Care Group level and based on Care Group training needs analysis.
4. That there is appropriate cross Service Care Group/Unit co-ordination and liaison to achieve compliance with this policy;
5. That adequate and appropriate support is made available to staff who are involved in/are the subject of a concern;
6. That staff trained in patient safety/concerns investigations within the Care Groups/Units are released or have their duties appropriately adjusted to enable them to undertake or support investigations when required;
7. That all information pertaining to individual concerns including the outcomes of all investigations are fully and accurately recorded in Datix Cymru, that all documents are saved against the Datix Cymru record, and all action plans are completed through the Datix Cymru system so that compliance can be easily monitored and reviewed;
8. That all necessary actions are taken to prevent re-occurrence of issues arising from both individual and aggregated concerns;
9. Appropriate communication and reporting of relevant information to all appropriate Groups/Committees;
10. That lessons are shared across services and the Health Board as relevant;
11. Create a culture across services where issues are resolved as they arise and informally as far as possible – not allowing unnecessary escalation or protraction of concerns
12. Ensure that 80% of concerns are responded to within 30 working days and no concerns receive a response later than 60 working days (Regulatory maximum time period);

13. The Care Group/unit Datix Cymru (patient safety) dashboard is reviewed regularly and core outcomes reported to Groups/Committees/Care Group/Unit meetings to assist decision making.

b. All Staff employed by the Health Board

All staff must:

1. Treat persons notifying concerns with respect and courtesy;
2. Address issues and concerns as they arise and escalate for assistance if unable to manage the matter;
3. Attend patient safety/ concerns training and Datix Cymru training pertinent to their roles and responsibilities;
4. Ensure that patient safety incidents that they are aware of are reported, no matter how minor they might appear. This ensures that the Health Board has the opportunity to take all appropriate actions under this policy including learning from such events and improving matters for the future;
5. Ensure they report patient safety incidents brought to their attention by patients and other persons. However, patients and other persons are equally entitled to complete and submit an incident report to the Health Board if they wish to do so. Staff should ensure assistance is given in such instances;
6. All staff should ensure they are aware of how to access copies of the Health Board's arrangements for handling Concerns, in all the formats, to enable them to satisfy any reasonable request made of them for this information;
7. Be open, honest and transparent at all times; and
8. Adhere to this Policy and supporting procedures.

c. Strategic oversight of the arrangements

A nominated Non-Officer Member must assume responsibility for maintaining a strategic overview of the operation of the Health Board's arrangements (under the Regulations), particularly as regards ensuring that:

- i. The Health Board complies with these arrangements and the officer supports a positive safety culture and commitment to being open;
- ii. The Health Board has arrangements in place to review the outcome of the investigation of any concern, in order to ensure that any deficiencies in actions or service provision that have been identified by the investigation, are acted upon and monitored;
- iii. Lessons learned are identified and disseminated throughout the Health Board in order to improve the services that it provides and to seek to reduce future risk.

In the case of CTM Health Board this role has been designated to the Chairperson of the Quality and Safety Committee.

d. Responsible Officer

The Regulations specify that the Responsible Officer is responsible for the effective day to day operation of the Health Board's arrangements for dealing with concerns in an integrated manner. The Executive Director of Nursing Midwifery and Patient Services is the Responsible Officer for CTM Health Board. [In relation to these regulations 'integrated manner' means that the process for dealing with concerns and claims management (where there is a duty under the Regulations to consider qualifying liabilities) are dealt with under a single governance arrangement.

The regulations allow for the functions of the Responsible Officer to be performed by the Executive Director of Nursing Midwifery and Patient Services or any person authorised by the Health Board to act on their behalf.

e. Senior Investigations Manager –

The Assistant Director of Quality and Safety is the Senior Investigations Manager for CTMU Health Board.

Under the Regulations, the Senior Investigations Manager is responsible for:

1. The handling and consideration of concerns in accordance with this Policy;
2. Performing such other functions relating to the handling and consideration of concerns as the Health Board may specify;
3. Ensuring co-operation with such other persons or bodies as may be necessary to facilitate the handling and consideration of concerns.

In relation to performing such other functions relating to the handling and consideration of concerns as the Health Board may specify', the Assistant Director of Quality & Safety is responsible for:

1. The operation of the Ombudsman and Complaints Team, Legal Services Department, Quality and Safety Team,
2. The development, integration and embedding of a comprehensive investigation and redress system for concerns,
3. Acting as the Health Board's Lead Investigation Officer; to lead, facilitate and provide advice on the investigation and analysis of concerns;
4. Overseeing the investigation of all serious concerns;
5. Personally investigating and analysing any individual concern when requested to do by the Executive Team;
6. Provide assurance to the Board on the Care Group/ units performance;
7. Ensure lessons learned are shared across Care Group/units.

f. Health Board – General

The Health Board is required by the Regulations to ensure that, at all times, the Senior Investigations Manager has a sufficient number of staff, of the required level of seniority and skills, to assist them in the carrying out of the functions that fall to the Senior Investigations Manager. Further, members of staff must receive adequate training to enable them to fulfil their responsibilities as specified.

The Health Board will ensure that all staff are informed about and receive appropriate training in respect of the operation of this Policy.

Non-Regulatory Responsibilities

g. Executive Team

The Medical Director and The Executive Director of Nursing Midwifery and Patient Services have joint responsibility for quality and safety and will provide leadership and support to ensure that the aims of this policy are achieved. They are both responsible for providing authority to admit a breach of duty in respect of their professional accountabilities and consider the Care Group/Unit Directors views on admissions.

h. Quality and Safety Committee

The Quality and Safety Committee:

- Considers Putting Things Right Policies to endorse approval by the Quality and Safety Committee and approves all relevant Standing Operating Procedures;
- Oversee compliance with the Health Boards Risk Management Strategy and Putting Things Right Policy and affiliated policies, as necessary to ensure compliance with the Strategy and Regulations;
- Receive reports at Corporate Directorate Level and Care Group/Unit Level in order that key issues can be identified and learning can be shared;
- Scrutinise themes and trends for escalation to the CTM Board;
- Receive exception reports on patient safety alerts and notices and agree actions required for action and monitoring;
- Highlight risk issues that require consideration at a Health Board wide level; and
- Highlight risks which require specialist review to the appropriate Corporate Group/Committee for consideration and the Executive Lead.

The purpose of the Quality & Safety Committee is to provide:

- Evidence based and timely advice to the Board to assist it in discharging its functions and meeting its responsibilities with regard to the quality and safety of healthcare; and
- Assurance to the Board in relation to the Health Board's arrangements for safeguarding and improving the quality and safety of patient centred healthcare in accordance with its stated objectives and the requirements and standards determined for the NHS in Wales.

The Quality & Safety Committee will receive a Quality and Safety Dashboard at each meeting, to support achievement of these objectives. Additional reports will be commissioned from appropriate areas as required.

6. General Principles for the Handling and Investigation of Concerns

The Health Board's arrangements for the handling and investigation of concerns are intended to ensure:

- a. A single point for logging complaints as required by Putting Things Right;
- b. The expectation of the person notifying the concern is established and their involvement in the process secured wherever possible;
- c. Concerns are properly investigated and responded to efficiently and openly, applying Health Board values;
- d. Persons raising concerns are treated with respect and courtesy; and advised of the availability of assistance to enable them to pursue their concern and where they may obtain such assistance, if it is required. Also the name of the person who will act as the Health Board contact throughout the handling of the concern;
- e. Whilst noting that Redress is not applicable to primary care providers; consideration is given to the making of an offer of redress where the Health Board's investigation into the matters raised in the concern reveals that there is a qualifying liability in tort;
- f. Persons notifying concerns receive a timely and appropriate response within the bounds of receiving the appropriate consent;
- g. Persons who notify the Health Board of concerns are advised of the outcome of the Health Board's investigation providing the appropriate consent has been received by the Health Board;
- h. Appropriate action is taken in the light of the outcome of the investigation and there is learning and improvement.

An action card for dealing with a complaint and in accordance with the requirements of the Regulations is in Appendix 1.

7. Who can Raise A Concern / Complaint

a. Persons who can notify Concerns / Complaints

Almost anyone can raise a concern and the Health Board will be under a duty to consider whether it can be investigated. However, it may not always be possible to share the full details of the investigation with the person raising the concern, for instance if they are not the patient or a person recognised as having authority to access the information.

A concern may be notified by:

1. People who are receiving or have received services from the Health Board,
2. Any person who is affected, or likely to be affected by the action, omission decision of the Health Board, in relation to the functions of the Health Board;
3. Any non-officer member of the Health Board, e.g. an independent member;
4. Any member of staff of the Health Board;
5. Any person acting on behalf of any person from the above categories (1 to 4) who has died, is a child, lacks the capacity under the Mental Capacity Act (2005) to notify the concern themselves or has requested the person to act as their representative.
6. Assembly Members and Members of Parliament

b. Concerns Notified by a third party

Within Putting Things Right guidance (2013), when a third party acts as a representative on behalf of another e.g. a child or someone who lacks mental capacity if there are reasonable grounds to conclude that they are not suitable to act on their behalf, for example because it does not appear to be in the patients best interests, then they must be advised in writing. However, an investigation into the issues raised may still need to be undertaken. In this instance the Health Board is under no obligation to provide a detailed response to the person who raised the concern, unless it is reasonable to do so.

c. Concerns raised on behalf of a child / young person

Where a concern is notified by a child, the Health Board must provide the child with any reasonable assistance that the child requires in order to pursue the concern. Specialist advocacy may be required and advice regarding accessing this is available from <https://www.meiccymru.org/about/>.

In many instances, someone else (parent/carer/guardian) will raise a concern on behalf of a child / young person. This does not remove the right of the child / young person to take the concern forward themselves with support. The Health Board must satisfy itself whether the child / young person wishes to raise the concern themselves, with support, or if they are happy for the person who raised the concern to represent them. If the child / young person is not willing to proceed with an investigation then a decision will need to be taken about proceeding and specialist advice sought if appropriate. Particular regard needs to be given to safeguarding issues, and it may be necessary to proceed with an investigation, even if a child appears unhappy to do so. The Health Board is under no obligation to provide a response to the person who raised the concern in the first instance.

d. Concerns Notified by Staff

Staff are required to report any concerns with a person's care or treatment via Datix Cymru (the Health Board's on-line Incident Reporting mechanism). Where the initial investigation determines there has been harm, the regulations require the Health Board to:

1. Notify the patient or his/her representative of the notified concern, and
2. Involve the patient, or his/her representative in the investigation of the concern

This notification and involvement will be undertaken in accordance with the Duty of Candour requirements.

Where it is considered that it would not be in the interests, this may be due to mental capacity or health status then a best interest meeting should be convened and the safeguarding team contacted. The Health Board is required to:

- i. Make a written record of this decision and the reasons for it, and
- ii. Keep the decision under review during the investigation of the concern

8. Matters & Concerns Excluded From Consideration Under The Policy

Not all concerns can be dealt with under the regulations. Matters excluded are set out in regulation 14 of Putting Things Right and examples include:

- a. A concern notified by a Primary Care Provider relating to the contract under which it provides Primary Care services - these are to be managed through the contractual arrangements;

- b. A concern notified by any member of staff relating to that person's contract of employment - these are to be managed through the Health Boards workforce procedures;
- c. A concern that is being or has been investigated by the Public Services Ombudsman for Wales;
- d. A concern arising out of an alleged failure of the Health Board to comply with a request for information under the Freedom of Information Act 2000 – these would be dealt with by the Information Commissioners Office;
- e. Disciplinary proceedings that the Health Board is taking or proposing to take, arising from the investigation of a concern notified and dealt with in accordance with this Policy- these would be via the Health Boards workforce procedures;
- f. A concern that is notified verbally and is resolved to the satisfaction of the person who notified the concern within 1 working day of the concern being notified;
- g. A concern with the same subject matter as a concern that was previously notified verbally and was resolved to the satisfaction of the person who notified the concern within 1 working day, unless the Health Board considers that it is reasonable to re-open the concern and undertake an investigation under this Policy;
- h. A concern previously considered under this Policy or the Health Board's previous Complaints Policy and Procedure;
- i. A concern that is/becomes the subject matter of Civil Proceedings. If court proceedings are issued when a concern is already under investigation in accordance with the regulations, all further investigation of the concern must stop;
- j. A concern that is/becomes the subject of a concern related to an Individual Patient Funding (IPFR) Request. Reference should be made to the Welsh Health Shared Services Committee IPFR policy.
- k. Police criminal investigation
- l. A concern that involves Safeguarding, this would be passed to the Safeguarding team for immediate action.

The Health Board will advise the person who notified the concern, as soon as reasonably practicable, in writing, of the reason(s) for any decision that the concern is excluded from the scope of the Regulations and, thereby, this Policy. However, this is not required in relation to a concern that was notified verbally and resolved to the satisfaction of the person who notified the concern within 1 working day of the concern being notified.

9. Time Limits For The Notification Of Concerns

The Putting Things Right regulations require a concern to be notified:

- a. Within 12 months of the date on which the subject matter of the concern occurred, or
- b. Within 12 months of the date on which the subject matter of the concern came to the notice of the patient. (Where a patient has opted to have a representative act on his/her behalf, this date is the patient's date of knowledge, NOT the date that the representative was informed of the concern by the patient).

To investigate a concern after this 12 month deadline, the Health Board must consider whether the person raising the concern had good reason not to notify the Health Board of the concern earlier and whether, given the time lapse, it is still possible to investigate the concern thoroughly and fairly.

However, a concern under these regulations may not be notified 3 or more years after the date on which the subject matter occurred or after the date that the subject matter came to the notice of the patient. The Health Board will, therefore, refuse to consider any such concern. (Where a patient has opted to have a representative act on his/her behalf, this date is the patient's date of knowledge, NOT the date that the representative was informed of the concern by the patient). If the person who raised the concern is a child at the time of injury the three year period does not begin to run until the individual reaches the age of 18 years and runs out on their 21st birthday.

If the Health Board makes an exception to this it must make it clear to the person who raised the concern that the investigation may be limited in some aspects based on the information available as key staff may have left the Health Board and memory in relation to the circumstances may be compromised.

10. Withdrawal of Concern

A concern may be withdrawn at any time by the person who notified it. The withdrawal can be communicated to the Health Board by written, electronic or verbal means.

Where a withdrawal is communicated verbally, the Health Board is required to write to the person to confirm the withdrawal.

The Health Board can continue to investigate any concern that has been withdrawn, should it be considered reasonable and necessary to do so.

11. Concerns that Involve Other Organisations

Where the Health Board is notified of a concern that also involves the functions of another organisations, (whether this is known by the person notifying the concern or not), the Health Board is required to seek the consent of the person to contact any other relevant organisations and notify it of the concern. This consent must be sought within 2 working days of the receipt of the concern and done at the same time as acknowledging the concern. However there may be occasions when it is not immediately evident that Primary Care contractors records need to be reviewed and comments sought.

Once consent is received, the Health Board is required to contact all other relevant organisations involved in the concern within 2 working days of the consent being received.

The Health Board must agree with the other organisations and person raising the concern which organisation will take the lead, co-ordinate the investigation and provide the response. All relevant organisations should be included in any meetings arranged to discuss the concern.

12. Concerns Notified To The Health Board Involving Primary Care Providers

Regulations 18-21 deal with concerns notified about services provided by a primary care provider under a contract or arrangements with the Health Board.

When the Health Board receives a concern, notified by or on behalf of a person who is receiving or has received services from a Primary Care provider, it is necessary to determine whether it is appropriate for the Health Board to consider the concern or whether it is more appropriate for the concern to be considered by the Primary Care provider that is the subject of the concern. Before making

this decision, and within 2 working days the Health Board must determine, from the person who notified the concern, whether:

- a. The concern has already been considered by the Primary Care provider, and if so, whether a response has been issued by the Primary Care provider that is in accordance with the requirements in the Regulations
- b. The person who notified the concern consents to details of the concern being sent to the Primary Care provider who is the subject of the concern.

If the concern has been investigated by the Primary Care provider and a response issued then the Health Board must not re-investigate it. The person must be advised of this and reminded of their right to take the matter to the Public Services Ombudsman for Wales.

If the concern has not been investigated by the Primary Care Provider and the Health Board considers this is a concern that it should investigate consent is required to allow the Health Board to send details of the concern to the relevant Primary Care provider who is subject of the concern. If consent is not provided the Health Board must not investigate the concern as it would not be possible to investigate without the co-operation of the Primary Care Practitioner, and the Practitioner should, in the interest of fairness know when a concern about them is being investigated.

If the Health Board decides that it is appropriate for it to deal with a concern, it is required to advise the person who notified the concern and the Primary Care provider of this decision within 5 working days, giving the reasons for this decision. Primary Care Providers are under an obligation to co-operate with investigations undertaken by the Health Board. However, the Health Board may not make any determination about the liability in tort of a Primary Care Provider. If such matters are alleged by the person raising the concern or arise during the investigation, the Primary Care Provider should be advised to involve their Medical Defence Organisation. The person raising the concern will need to be notified that the Health Board cannot become involved in those aspects of any concern about a Primary Care Provider.

If the Health Board decides that it is more appropriate for the concern to be dealt with by the Primary Care provider, the Health Board is required to advise the person who notified the concern and the Primary Care provider of this decision and why the decision has been made. The person raising this concern may be unhappy with this decision and should be informed as part of this decision letter of their right to take their concern to the Public Services Ombudsman for Wales.

When the Primary Care provider receives the notification of the Health Board's decision, the Primary Care provider must deal with the Concern in accordance with the Regulations.

13. Handling Of Concerns

a. Verbal Concerns / Complaints

1. Where a concern is notified verbally, the member of staff to whom the concern has been notified must make every effort to respond to that complaint there and then. If unable to do so to the satisfaction of the complainant they must escalate to someone more senior e.g. Ward Manager, On-call Manager, and Departmental Manager etc. All attempts should be made to deal with these issues as soon after they arise taking no longer than the next working day. These should be documented as early resolution concerns using Datix Cymru.
2. If the complaint is resolved to the satisfaction of the complainant then the person dealing with the complaint must make a written record of the concern and offer a copy of the written record to the person who notified the concern.

b. Acknowledgment of Concerns

Complaints managed under Putting Things Right must acknowledge receipt of the concern within 5 working days of the day on which the concern is received. The acknowledgement may be made in writing or electronically, depending upon how the concern was notified to the Health Board.

Where the concern is notified verbally, the Health Board is required to acknowledge the concern in writing, outlining what the issues were and what has been agreed in relation to matters for investigation.

For care & treatment concerns attempts should be made to contact the person who raised the concern for a discussion prior to the acknowledgement being sent. This should be undertaken by a responsible officer for the area/ service concerned. The responsible officer should thank them for raising the concern, offer an apology and where the officer considers it appropriate offer a meeting to discuss the concerns further. Even where a meeting is being arranged, the concerns team will still issue a written acknowledgement outlining who to contact while the investigation is undertaken, in addition:

1. The manner in which the Health Board will handle the investigation, including consent to the use of medical records;

2. The availability of advocacy and support services that may be of assistance to the person in their pursuit of the concern;
3. The period within which the Health Board is likely to complete the investigation of the concern and send a response to the person.

Further details on investigating and responding to concerns is provided in Appendix 1.

c. Consent

Where the person has raised the concern then in doing so, they can be deemed to have given implied consent to an investigation. This will also apply if a concern is raised by a representative who has shown proof that they are legally entitled to act for the patient/data subject (e.g. the representative has a Power of Attorney and the terms of the Power of Attorney have been met). However, in order for individuals to be clear in the knowledge that their medical records may need to be accessed, and therefore shared with the person acting on their behalf, this should be explained in the acknowledgement letter so that they have the opportunity to indicate if they do not want their health records accessed .

Where a third party has raised a concern, then the patient or their representative will be asked to give written consent to allow access to medical records and the conduct of an investigation.

d. Grading of Concerns

The All Wales Grading Framework is based on a matrix developed by the former National Patient Safety Agency and is used to assess and manage incidents. The grading of a concern should be assessed on receipt of the concern and reviewed following the investigation.

This matrix will be adopted to determine the level of investigation required in dealing with all types of concerns in order to promote a consistent approach across the Health Board and to ensure a proportionate investigation (Appendix 2).

e. Quality of Response

It is essential that all responses are full, comprehensive, clear and answer the concerns raised. The response needs to be in layman's terms ensuring a meeting is offered on receipt of the responses and information is provided on how to access the Public Service Ombudsman office (Wales). The senior Care Group/Unit team will ensure that all responses are thoroughly quality assured, using the quality assurance checklist (Appendix 4) and approve the final response for sharing with the complainant. All staff who undertake quality assurance checks for concerns

must receive training on this process which can be accessed via the concerns team.

Regulation 24 requires the Health Board to take all reasonable steps to send the response to the person who notified the concern within 30 working days, beginning on the day that the notification of the concern was first received. It is essential the Concerns team advises the person who raised the concern of the predicted timescale for a response. If the Health Board is unable to provide a response within 30 working days, the following actions are required:

1. A written explanation setting out the explicit reasons for the delay must be provided to the person who raised the concern, with estimation or anticipated date for completion of response.
2. Some responses may take up to 60 working days (3 months), where a serious patient safety investigation is required. Rarely an investigation may take up to 6 months, however where this is the case close contact with the complainant must be maintained to provide regular updates of the stage of the investigation. Responses should not be sent later than 6 months, from the day that the notification of the concern was first received.
3. Timescales are reported at service, Care Group/unit and at corporate level through the management structures.

14. Learning from Concerns

The Health Board will ensure that it has arrangements in place to review the outcome of any concern that has been subject to an investigation under the Regulations, in order to ensure that any deficiencies in its actions or its provision of services, identified during the investigation, are:

1. Recognised, acknowledged, owned and acted upon
2. Where improvement requires embedding, an improvement plan will be developed using the template action plan in Datix Cymru within the Datix Cymru Action Plan module; and
3. Reviewed and reported regularly within the Care Groups, as highlighted within the Listening and Learning Framework, to ensure improvements are established minimizing the risk of reoccurrence.

Learning lessons throughout the Health Board and taking action to ensure any necessary improvements are made is critical to avoid such deficiencies recurring.

The Health Board has a number of mechanisms for sharing learning from patient experience and concerns, eg. Alerts, newsletters, intranet, training, meetings using the multi-disciplinary team forums within the Care Group/units for shared learning and improvement.

15. Being Open / Duty of Candour

A culture of openness, transparency and candour is widely associated with good quality care. The Health Board requires an organisational duty of candour requiring staff to be open and honest with patients and service users when things go wrong. The duty requires the Health Board to follow a process when a service user suffers an adverse outcome which has or could result in unexpected or unintended harm that is more than minimal and the provision of health care was or may have been a factor. There is no element of fault, enabling a focus on learning and improvement, not blame.

16. Reopening Complaints

In the event that a complainant is dissatisfied with their response and there are no new issues to investigate then the complaint will not be reopened but a meeting with the complainant will be offered. Where the complainant remains dissatisfied then he/she will be advised to refer to the Public Services Ombudsman of Wales.

17. Alternative Dispute Resolution

Some complaints may be resolved by using alternative dispute resolution (ADR), such as mediation, facilitation or conciliation. This approach is often useful when the person who raised the concern is upset or there is unease between the Health Board and the person raising the concern. An ADR panel will be convened where:

- Staff or practitioners are having difficulty in dealing with the concern
- When the person who raised the concern feels anxious that the approach of the concerns team/lead person is not impartial;
- When there are misunderstandings with relatives, during the treatment of a patient.

ADR can lead to a 'shared view' of the situation including their differences. The Terms of reference for an ADR panel are enclosed in Appendix 5.

18. Where a Qualifying Liability does or may exist (Redress)

Regulation 26 requires that where the Health Board's investigation of a concern determines that a qualifying liability exists or may exist, it is required to determine whether or not an offer of Redress should be made. All responses where it is considered that there is a qualifying liability or a possible qualifying liability, will require review by the legal team.

Redress can take the form of:

- A formal apology.
- Remedial action.
- Investigation and explanation.
- Financial compensation up to £25, 000.00.

To establish liability, the following elements must be met:

- a. That the Health Board had / has a duty of care to the person. A legal duty of care arises when the health care system accepts the patient.
- b. The duty of care has been breached i.e. the standard of care / treatment provided fell below the expected standard.
- c. Causation of damage. Did the healthcare provider's acts or omissions caused harm to the patient as a result of the breach of duty of care?

If the Health Board considers that the qualifying liability justifies financial compensation exceeding £25,000, the Health Board must not offer Redress in the form of financial compensation under the Regulations. The Health Board may, however, make an offer of settlement outside of the provision of the Regulations.

A patient, or his or her representative, has 6 months from the date the offer is made, to respond to an offer of financial compensation made by the Health Board. After 6 months, the liability will no longer be considered as being the subject of an application for Redress.

In some situations, this can be extended to 9 months, please refer to the Putting Things Right Guidance, (2013).

Redress is not available and must not be offered in relation to a liability that is, or has been, the subject of Civil Proceedings. If Civil Proceedings are issued during the course of the Health Board considering Redress, the Health Board must cease all consideration of Redress and must advise the person who notified the concern accordingly.

Where the Care Group/ unit management team determine a breach of duty has occurred or considers this may be likely, the case will be discussed at the weekly Redress Meeting.

19. Confidentiality

Information contained within concerns falls within the definition of personal data contained within the General Data Protection Regulation (2016). The Health Board also has duties under the requirements of Caldicott and the Human Rights Act 1998 in respect of the right to privacy and also the Freedom of Information Act 2000 in respect of openness.

Information on concerns should not be disclosed/copied/ shown to any external agency without the permission of the Responsible Officer or nominated deputies. All requests for access to such information should, therefore, be directed to the appropriate Manager, or nominated deputy, for the service area that is the subject of the concern, in the first instance.

NHS Wales has adopted the Confidentiality: Code of Practice for Health and Social Care in Wales. All staff have an obligation of confidentiality regardless of their role and are required to respect the personal data and privacy of others. Staff must not access information about any individuals who they are not providing care, treatment or administration services to in a professional capacity. Rights to access information are provided for staff to undertake their professional role and are for work related purposes only.

Further information where required can be found via the organisation's Privacy Policy, and the Information governance Policy.

20. Managing Media Interest / Media Communications

The management of media interest/ in relation to incidents, either individually or generally, will be undertaken by the Health Board Communications Department

21. Disability and Special Requirements of a Complainant

Immediately a complainant identifies a disability or special requirements in relation to communication, every effort must be made to make reasonable adjustments to accommodate the special request/requirement. Once agreed this should be documented in Datix Cymru and shared with all staff who will communicate with the individual.

22. Dealing with Unreasonable Demands

People raising concerns have the right to be heard, understood and respected. On occasions there may be times when persons raising the concern out of character and become determined, forceful, and angry and make unreasonable demands of staff.

If staff encounter situations where person behave in an unacceptable manner towards them, then they should report to their line manager for support and advice. The complaints manager should be informed and this must be reported

on Datix Cymru. The complaints manager will provide verbal and written guidance on dealing this type of behaviour. Please see Appendix 3.

a. What is unreasonable, unacceptable aggressive or abusive, violent behaviour?

- Behaviour that produces damaging or harmful effects, physically or emotionally on other people.
- Persistent unacceptable behaviour – behaviour that is deemed unacceptable within one event or on a number of occasions within a period of time.

b. Examples of unacceptable or aggressive or abusive behaviour:

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

23. Training

Whilst there are specific elements to the effective and efficient management of concerns which require training, the most enabling aspect of achieving this relates to staff in every part of the organisation fully embracing the Health Board's values in their interactions with everyone they come into contact with including, patients, relatives, carers and colleagues.

The different levels of training are outlined in the concerns training plan which outlines the training specific to Putting Things Right. At level 1 training is provided at staff induction and management of complaints is available via the learning portal on the Electronic Staff Record (ESR) site.

Level 2 training is specifically aimed at staff undertaking patient safety and grade 4 and 5 complaint investigations.

Additional training needs are identified through management structures and processes within the localities, e.g. via the Performance Annual Development Review (PADR) process.

The concerns team undertake local departmental level training and also at wider Health Board level in the form of annual learning events. Specific professional

groups also receive training, e.g. the new junior Doctors and new consultants. The concerns team are reactive to the Care group/unit training needs analysis to meet training requirements.

Appendix 1

Action Card for dealing with Complaints

Immediately
<ul style="list-style-type: none"> • Listen to the concerns raised, Say Sorry and acknowledge what has happened. Consider if there is harm and if any immediate make safe action is required. An apology, shall not of itself amount to an admission of negligence or breach of statutory duty. • Delayed or poor communication makes it more likely that a person will seek information in a different way such as complaining or taking legal action and this delays resolution and/or redress, wherever this is possible. • The way you say sorry is just as important as saying it. An apology should demonstrate sincerity and tailored to the individual's needs. • Stay calm, polite, use the person's name, make eye contact and speak calmly • Remember the person may be prompted by distress, bereavement, anxiety and frustration • Provide a copy of the Putting Things Right Leaflet in a suitable format
Early Resolution
<ul style="list-style-type: none"> • Every effort to respond to any concerns at the time they are raised should be made. If unable to do so to the satisfaction of the person raising the concern they must escalate to someone more senior e.g. Ward Manager, Departmental manager etc. All attempts should be made to deal with these issues as soon after they arise taking no longer than 24 hours. These should be documented as early resolution concerns in Datix Cymru. • If the complaint is resolved to the satisfaction of the complainant then the person dealing with the complaint must make a written record of the concern and offer a copy of the written record to the person who notified the concern. • Staff must advise people how to progress their complaint to be managed through Putting Things Right, if they are not satisfied with the outcome of their complaint at the end of the early resolution stage. • Frontline staff should be trained and encouraged to provide appropriate information on advice and advocacy support at this stage of the complaints process. • Training is available at induction and also via ESR. Staff are required to identify their training needs via the PADR process.
Complaints managed under Putting Things Right Regulations
<p>Where the person wishes to have their complaint managed through Putting Things Right or where there is an allegation of harm then the complaint must be managed under the Putting Things Right regulations. The complaint must be logged on Datix Cymru and formally acknowledged within 5 working days of the day on which the complaint was received. The acknowledgement may be made in writing or electronically, depending upon how the complaint was notified to the Health Board.</p> <p>Attempts should always be made to contact the person who raised the concern to have a discussion with them prior to the acknowledgement going out to thank them for raising the concern, offer an apology that they have needed to do so, and offer a meeting with the manager of the area or clinicians responsible for services concerned. The written acknowledgement must confirm this.</p>

The person making the complaint must be advised of timescales for investigating their concerns. This is within **30 working days**, however very occasionally it may take up to 60 working days where a serious patient safety investigation is required.

All formal complaints must be managed under the Putting Things Right regulations and handled by the Care Group/unit's central governance team. The complaint will be graded to decide on the appropriate level of investigation, see Appendix 2.

Appendix 2



Grading Framework for Complexity of Complaint

Grade	NPSA level of harm	Examples of concerns	Redress Potential
1	<p>No harm</p> <p>Impact Prevented – any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to people receiving NHS funded care OR Impact not prevented – any patient safety incident that ran to completion but no harm occurred to people receiving NHS-funded care.</p>	<p>Concerns which normally involve issues that can be easily / speedily addressed, with no harm having arisen. For example:</p> <ul style="list-style-type: none"> • outpatient appointment delayed, but no consequences in terms of health • difficulty in car parking • Concerns which have impacted on a positive patient experience 	Highly unlikely
2	<p>Low harm</p> <p>Any patient safety incident that required extra observation or minor treatment and caused minimal harm, to one or more persons receiving NHS-funded care.</p>	<ul style="list-style-type: none"> • Concerns regarding care and treatment which span a number of different aspects/specialities • Increase in length of stay by 1 - 3 days • Patient fall - requiring treatment • Requiring time off work - 3 days • Concern involves a single failure to meet internal standards but with minor implications for patient safety • Return for minor treatment, e.g. local anaesthetic 	Unlikely
3	<p>Moderate harm</p> <p>Any patient safety incident that resulted in a moderate increase in treatment and which caused significant but not permanent harm, to one or more persons receiving NHS-funded care.</p>	<ul style="list-style-type: none"> • Clinical / process issues that have resulted in avoidable, semi permanent injury or impairment of health or damage that require intervention; • Additional interventions required or treatment / appointments needed to be cancelled; • Readmission or return to surgery, e.g. general anaesthetic; • Necessity for transfer to another centre for treatment / care • Increase in length of stay by 4 -15 days • RIDDOR Reportable Incident • Requiring time off work 4 -14 days • Concerns that outline more than one failure to meet internal standards • Moderate patient safety implications • Concerns that involve more than one organisation 	Possible in some cases
4	<p>Severe harm</p>	<ul style="list-style-type: none"> • Clinical process issues that have resulted in avoidable; semi-permanent harm or impairment of health or damage leading to incapacity or disability; • Additional interventions required or treatment needed to be cancelled; 	Likely in many cases

	Any patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS-funded care.	<ul style="list-style-type: none"> • Unexpected readmission or unplanned return to surgery; • Increase in length of stay by >15 days • Necessity for transfer to another centre for treatment / care • Requiring time off work >14 days • A concern, outlining non compliance with national standards with significant risk to patient safety • RIDDOR Reportable Incident 	
5	<p>Death</p> <p>Any patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS-funded care, or Any patient safety incident that directly resulted in the death (or severe harm) of one or more persons receiving NHS-funded care.</p>	<ul style="list-style-type: none"> • Concern leading to unexpected death, multiple harm or irreversible health effects • Concern outlining gross failure to meet national standards • Normally clinical/process issues that have resulted in avoidable, irrevocable injury or impairment of health, having a lifelong adverse effect on lifestyle, quality of life, physical and/or mental well-being. • Clinical or process issues that have resulted in avoidable loss of life • RIDDOR Reportable Incident 	Very Likely

Appendix 3

ACTION CARD

Dealing with people who make unreasonable demands relating to concerns

People raising concerns have the right to be heard, understood and respected. However, there may be times when the distress of a situation leads to the person raising a concern to act out of character and become determined, forceful, and angry, and make unreasonable demands of staff or (rarely) use threatening behaviour and even resort to violence.

People who are unhappy about the outcome of the investigation of their concern, despite being advised about other avenues available to them, may also show aggression towards staff or continue to persistently pursue their concerns by phoning, writing or in person. The following steps may be considered and further information is available in the Putting Things Right Guidance- Appendix L.

Action Required

Notify and seek support from the Concerns Team

The Concerns Team will-

Put an arrangement in place whereby calls can only be received at set times on set days and **one member** of staff will be allocated as a contact point for written or verbal communication.

Restrict contact to written correspondence only.

Advise to only make appointments to meet with the complainant if there is no other way of communicating with them. Also advise to never meet them alone and always in working hours within a NHS facility where other staff are available for support. If there are threats or use of physical violence the incident should be reported to the police.

At each stage, it should be made clear to the person what actions are being taken and why, and outlined in a letter to the complainant from the concerns team.

Where previous concerns have been addressed, the complaints file should be closed and if new issues arise it should be explained that this will be managed as a new complaint. Any new correspondence will be acknowledged and the PTR Regulations followed in the usual manner.

Reporting Violent or Aggressive Behaviour

Incidents where violence and/or aggression occur **must** be reported and recorded via local reporting mechanisms.

Key Quality Assurance Questions for Consideration

COMPLAINT HANDLER QUALITY ASSURANCE CHECKLIST

Staff name:			
Datix reference			
Supervisor:			
Date of assessment:		Complete	Feedback

Action assessed	Assessed by	Comment
Concern acknowledged within 2 working days	Datix Progress Notes and Documents	
Introduction call completed and issues fully scoped	Datix Progress Notes and Documents	
Correct Clinicians identified for comments	Memo details saved to Datix documents for review	
Memo issued within 4 working days	Memo details saved to Datix documents for review	
Comments chased after 10 working days (if applicable)	Datix Progress Notes and Documents	
Delays raised in weekly Care Group review (if applicable)	Datix Progress Notes	
Does The Final Response Letter address all elements of original concern?	View original concern and memo to Clinicians to compare	
Is the language used appropriately sensitive to the patient and / or their family reading the response?	Review of Final Response Letter	
Is the response written in Layman's terms?	Review of Final Response Letter	
Does the response include all required PTR wording?	Review of Final Response Letter	
Has the record been closed appropriately?	Ensure all dates have been correctly entered	
Have progress notes been updated to show a full audit trail?	Cross reference Documents with Progress Notes	
Have all documents been uploaded to the Document section?	Cross reference Progress Notes with Documents	

Appendix 5

Alternative Dispute Resolution Panel –Terms of Reference

1. INTRODUCTION

Cwm Taf Morgannwg University Health Board manages Complaints in line with the requirements of *Putting Things Right (2011)*. The management of complaints is reviewed regularly, to take account the guidance provided by the Welsh Risk Pool safety and learning networks which includes network groups for complaints handling, Public Services Ombudsman of Wales improvement work, claims management and Redress.

Some complaints may be resolved by using alternative dispute resolution (ADR), such as mediation, facilitation or conciliation. This approach is often useful when the person who raised the concern is upset or there is unease between the Health Board and the person raising the concern. An ADR panel will be convened where:

- Staff or practitioners are having difficulty in dealing with the concern
- When the person who raised the concern feels anxious that the approach of the concerns team/lead person is not impartial;
- When there are misunderstandings with relatives, during the treatment of a patient.

ADR can lead to a 'shared view' of the situation including their differences.

3. PURPOSE

The purpose of the Alternative Dispute Resolution Panel is to provide a forum of expertise for reviewing an unresolved complaint, to ensure that complaints are managed in line with the Regulations, and in a manner which minimises clinical, financial and organisational risks.

The panel will provide assurance to the complainant of further review of the concerns raised to assess if any further action by the health board is required.

The Panel will assess the complaint and the quality of response as well as any further communications between the complainant and the Health Board to assess if any further action is required.

4. SCOPE

The scope of the Panel is:

1. To take an independent overview of the complaint, the response and any other forms of communication between the complainant and the Health Board. Consideration will be given to:
2. The continued concerns of the complainant, the response already issued, any gaps in the continued concerns and the response.
3. Compliance with the Putting Things Right guidance and regulations
4. The panel will undertake a detailed analysis and scrutiny of the complaint, to assess the degree of effective management, including evidence of robust proportionate investigation, learning and improvement where required.

As part of this work, the Panel will review confidential issues and is required to work under the General Data Protection Regulations (2016) and the requirements of Caldicott and the Human Rights Act 1998 in respect of the right to privacy and also the Freedom of Information Act 2000 in respect of openness. As such, all reports and action plans should be clearly marked as confidential. Members of the Panel must raise concerns regarding confidentiality issues at any time during the meeting if they feel that an individual's position is being compromised or they need to declare an interest.

5. MEMBERSHIP

Executive Director of Nursing, Midwifery and Patient Services or nominated deputy

Assistant Director of Safety and Quality

Medical Director or nominated deputy

Board Secretary/Corporate Director

Head of Concerns and Business Intelligence

Invited colleagues to attend as required in order to present and to discuss specific issues, such as representatives from the relevant service areas and patient advocacy services, e.g. Community Health Council Representative, legal and risk services, violence and aggression lead.

6. QUORUM

A quorum will include: one Executive Director, Board secretary/ Corporate Director and one other member.

7. FREQUENCY OF MEETINGS

The Panel shall meet when Alternative Dispute Resolution is considered by the Assistant Director of Quality and Safety. Minutes and action points from meetings will be circulated within 7 days following the meetings. Papers for meetings will be circulated 7 days prior to the scheduled meeting date.

8. AUTHORITY

The Panel will require authorisation from the complainant to hold a panel and written consent will be obtained.

10. REVIEW

These Terms of Reference shall be adopted by the Alternative Dispute Scrutiny Panel and will be subject to review every two years by the Concerns scrutiny panel.